

The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*

Additional Q&A dated 23 March 2018

Update in December 2020:

Following a review, the guidance on *Clostridium botulinum* as updated in December 2020 no longer applies to vacuum and modified atmosphere packed (VP/MAP) chilled fresh beef, lamb and pork, without added ingredients or further processing beyond cutting, packing, chilling, freezing and quick-freezing.

However, the guidance does still apply to any beef, lamb or pork that is further processed such as minced, cooked or mixed with any other ingredients such as herbs, spices or curing salts. The guidance applies to these and to any other VP/MAP chilled foods.

This Q&A should be read with the guidance as updated in December 2020 in mind.

26.Q: When will there be a consultation for “The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to nonproteolytic *Clostridium botulinum*?”

A: The FSA [publicly consulted on the guidance](#) from 30 June 2016 to 25 August 2016. The FSA, in conjunction with FSS, also publically consulted on the guidance from 1 October 2020 to 11 November 2020. Any further review will be undertaken when external research is made available to us and can be assessed by the ACMSF and ourselves.

27.Q: Does the FSA/FSS guidance indicate whether separate risk assessments need to be made for each food type in relation to *C. botulinum*?

A: Question 1 in the guidance answers this point and specifically highlights that

non-proteolytic *C. botulinum* must be considered a potential risk for raw and ready to eat VP/MAP chilled foods, and incorporated into HACCP based procedures.

28.Q: How should FBOs label sales to mass caterers and would this differ to sales to secondary processors?

A: The need to apply labels indicating the durability of foods only affects FBOs that produce pre-packed products intended for direct sale to the consumer or to mass caterers. However, all FBOs must ensure that other FBOs that purchase their goods are provided with sufficient information to enable them, where appropriate, to meet their obligations in providing a durability label. For example, in the case of meat, this may take the form of labels on carcasses indicating the kill date, or on kill dates indicated on the commercial document.

29.Q: Does imported meat have to adhere to the 10-day shelf life? (The guidance on *C. botulinum* as updated in December 2020 no longer applies to VP/MAP chilled fresh beef, lamb and pork as described above.)

A: Food businesses sourcing their products from other countries should seek assurances from the suppliers that food safety controls are in place for vacuum packed chilled products that are to be stored and transported between 3°C and 8°C in respect of non-proteolytic *Clostridium botulinum*, to ensure that they will remain safe during their shelf life if longer than 10 days.

30.Q: Can vacuum packed fresh meat (other than VP/MAP chilled fresh beef, lamb and pork as described above) be stored at or below 3°C for more than 10 days? (The guidance on *C. botulinum* as updated in December 2020 no longer applies to VP/MAP chilled fresh beef, lamb and pork as described above.)

A: Question 5 in the [vacuum packing guidance](#) addresses this point specifically and was amended in June 2017 after consultation with industry.

31. Q: Does the 10-day shelf-life count start once the temperature of vac pack product reaches 3 degrees C?

A: The shelf life of a product needs to be determined to ensure the product remains safe and fit for human consumption throughout all stages of production, processing and distribution up to and including use by the final consumer. One of the considerations to be made includes the potential for non-proteolytic *C. botulinum* to

grow and produce its toxin.

In relation to *C. botulinum* specifically, storage temperatures below 3°C are considered to prevent growth and toxin production. As stated above, other factors come into play in the shelf life of foods, so even food stored below 3°C may have a shelf life below 10 days anyway.

32.Q: Was raw meat only included into the scope of the guidance during the 2016 review? Why was VP/MAP fresh chilled beef, lamb and pork excluded from the scope of the guidance in December 2020?

A: Raw meat had always been included within the scope of the guidance. It had always been clearly stated that the guidance applied to all raw foods. The review in 2016 determined that raw meat should be named specifically as to allay any previous ambiguity that “raw food” was not encompassed by it. [Question 2 of VP/MAP guidance refers].

In 2020 the FSA, together with FSS, undertook a review of available evidence on the shelf-life of VP/MAP chilled fresh beef, lamb and pork and concluded that it was not proportionate to continue to include VP/MAP chilled fresh beef, lamb and pork in the guidance on non-proteolytic *C. botulinum*. The research and evidence review did not identify any report of an outbreak of foodborne botulism linked to VP/MAP chilled fresh beef, lamb and pork over several decades either in the UK, including before the guidance was issued, or internationally.

However, the guidance does still apply to any beef, lamb or pork that is further processed such as minced, cooked or mixed with any other ingredients such as herbs, spices or curing salts. The guidance applies to these and to any other VP/MAP chilled foods.

FBOs producing the specific VP/MAP chilled fresh beef, lamb and pork which is outside the scope of this guidance will be responsible for identifying and applying a safe shelf-life in relation to non-proteolytic *C. botulinum* in line with their existing food

safety management systems, in the same way they do for other types of food¹.

It is recognised that small and medium sized food businesses may not have resources and expertise for identifying a suitable shelf-life for specific VP/MAP chilled fresh beef, lamb and pork that are outside the scope of this guidance. Therefore, FBOs, including small and medium sized food businesses, that voluntarily want to apply the guidance to their VP/MAP chilled fresh beef, lamb and pork that are outside the scope of this guidance may do so. In these circumstances FBOs which are maintaining good hygiene practice may apply up to a maximum 13 day shelf-life for their VP/MAP chilled fresh beef, lamb and pork in relation to *C. botulinum*, should they wish to do so, without further verification or validation of the 13-day shelf-life for *C. botulinum*. The FBO should follow this guidance in the same manner as it applies to 10 days but may apply 13 days. The ACMSF on 30 January 2020 [endorsed a recommendation of its subgroup's report on *C. botulinum*](#) that a 13 day maximum shelf-life may be applied for VP/MAP chilled fresh beef, lamb and pork. The shelf-life should not be restarted if the VP/MAP chilled fresh beef, lamb and pork is subject to a further re-wrapping under vacuum or modified atmosphere, unless appropriate controls are applied as set out in this guidance.

33.Q: If a product comes in with a process by date, what validation do we need to have from the supplier for the product?

A: The indication “process by” is not recognised in legislation. However, “processing” is defined in Regulation 852/2004 as any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating,

¹ Examples of industry guides that FBOs may use include: the “Guidelines for Setting Shelf life of Chilled Foods in relation to non-proteolytic *Clostridium botulinum*” issued by Chilled Food Association/Quadram Institute/Leatherhead Food Research/Meat & Livestock Australia/British Retail Consortium in 2018, and “Shelf Life of MAP and VP Raw Meat Products in Relation to non-proteolytic *Clostridium botulinum*” issued by BRC Global Standards in 2018.

extraction, extrusion or a combination of those processes. Any food business operator that receives product with usage information that is not clear should seek confirmation of what that means.

It is the producers along the food chain who need to set the shelf life of their products. Subsequent food business operators may wish to ask for evidence of the validation for this to satisfy their own food safety management procedures (for example, as a pre-requisite to become listed suppliers) but there is no obligation to do so.

For susceptible products that rely on controlling factors for *C. botulinum* other than storage at temperatures below 3°C, if those controlling factors are not already validated by their supplier, FBOs should assess and validate each individual product against the risk from *C. botulinum* and, where the shelf-life is greater than 10 days without a sufficient single controlling factor, provide evidence of the safety of the product throughout its entire shelf-life in respect to non-proteolytic *C. botulinum* (e.g. via modelling, challenge testing or other appropriate means of validation).

34.Q: If meat is kept under vacuum pack conditions below 3 °C throughout the chain, please confirm it is exempt from the Guidelines and the shelf life can be greater than 10 days. (The guidance on *C. botulinum* as updated in December 2020 no longer applies to VP/MAP chilled fresh beef, lamb and pork as described above.)

A: As stated in paragraph 16 under the heading “Purpose of the guidance” within the VP/MAP guidance. “The microbiological safety concerns summarised here are focussed on the control of non-proteolytic *Clostridium botulinum*, which is able to grow and produce toxin at 3°C and above. Foods stored at less than 3°C are outside the scope of this guidance.”

35.Q: Where a re-packer takes primal meat and cuts it and re-vacuum packs, can the ten days shelf-life start when the meat leaves the re-packers’ controlled temperature of below 3 °C? (The guidance on *C. botulinum* as updated in December 2020 no longer applies to VP/MAP chilled fresh beef, lamb and pork as described above.)

A: Question 24 of VP/MAP guidance refers.

36. Q: Can meat that has gone above 3°C but not over 8 °C at the re-packers have its shelf life adjusted so that it falls within a total of 10 days

of temperature being above 3°C? (The guidance on *C. botulinum* as updated in December 2020 no longer applies to VP/MAP chilled fresh beef, lamb and pork as described above.)

A: Question 24 of VP/MAP guidance refers. “For products that were originally given a shelf-life of 10 days by the manufacturer, the FBO who is re-wrapping the product needs to ensure adequate controlling factors are in place before applying a re-wrapped shelf-life of greater than 10 days. The FBO may need to contact the manufacturer to determine what controlling factors they put in place for their product. Importantly, the shelf-life of the re-wrapped product should not exceed the shelf-life given to the original product unless additional controls are applied before it is re-wrapped. All FBOs extending the shelf-life of the product will need to be able to demonstrate that it is safe.

The shelf-life given to the re-wrapped VP/MAP product will depend on the controlling factors used by the manufacturer when applying the original shelf-life of greater than 10 days. For instance, if the controlling factor used in addition to chilled storage was a heat treatment of 90°C for 10 minutes or equivalent, due to the potential for recontamination with non-proteolytic *C. botulinum* spores between opening and rewrapping, the shelf-life applied to the re-wrapped product should not be greater than 10 days, unless other controlling factors are introduced.

If the controlling factors used in addition to chilled storage are factors other than heat treatment such as pH, salt or aw; these are unlikely to have changed following opening and re-wrapping, unless for example other ingredients are added to the product. If the Competent Authority is satisfied that there is evidence that these controlling factors have not changed and remain sufficient to control non-proteolytic *C. botulinum* and any other relevant microorganisms, then the shelf-life applied to the re-wrapped product may be greater than 10 days, but cannot exceed the shelf-life given to the original product. If information on the controlling factors used by the original manufacturer to apply a shelf-life of greater than 10 days cannot be obtained, the FBO would be best placed to apply a maximum 10 days shelf-life to the rewrapped product unless the FBO can identify or introduce additional controlling factors. Again, the shelf-life of the re-wrapped product should not exceed the shelf life given to the original product.”

37. Q: Once a business opens the pack and trays it up, normal industry practice is to have an internal shelf life of 3 days (so long as that is within the manufacturer's shelf life). As this product has now been exposed to oxygen, could the product be kept longer than the Guidance UBD of 10 days for an additional 3 days within a company's FSMS day dot scheme? Is there a possible double date that could be added to the pack to allow this to occur (within the overall life from the first primal packer)?

A: The packaging should have instructions for use on it which would detail this scenario e.g. "once opened use within XX days"

FBOs should be reminded that they should follow manufacturer's instructions and this should be incorporated into the businesses HACCP.

38. Q: If retailers are giving a shelf-life longer than 10 days to vac packed meat on sale in stores do they have some other means of control to obtain a shelf life greater than 10 days in a vac pack above 3°C and to tolerate temperature abuse from consumers? (The guidance on *C. botulinum* as updated in December 2020 no longer applies to VP/MAP chilled fresh beef, lamb and pork as described above.)

A: It may be that they have other controlling factors that enable them to extend the shelf life, such as nitrites. Question 8 of VP/MAP guidance refers.

"The guidance covers the main controlling factors that a FBO can apply in addition to chill temperatures to enable a shelf-life of greater than 10 days. In addition to these, it is also possible to use a lower level of factors (i.e. heat treatment, pH, salt concentration and aw) in a food to achieve a combined preservation effect or use additional preservatives such as nitrite to comply with additive legislation Regulation EC No 1333/2008. Where a lower level of factors is used, each factor is not able to inhibit the growth of *C. botulinum* and production of toxin on its own but the safety of the food with respect to non-proteolytic *C. botulinum* relies on the combined effect of all factors. Where a combination of factors is used, it is necessary to illustrate that the preservation system chosen can consistently prevent growth of non-proteolytic *C. botulinum* and toxin production; this may be done by predictive modelling, challenge testing or other appropriate means of validation.

In relation to other preservatives, the only controlling factors in addition to heating at

90°C for 10 minutes, which are currently recommended to inhibit the growth of *C. botulinum* and production of toxin are salt, pH and aw and these are explained in more detail in the FSA/FSS guidance. There are other preservatives which will have an impact on the growth of *C. botulinum*, such as nitrite, sorbic acid, benzoate and lactate. Whilst there may not be sufficient data to allow a recommendation for any of these preservatives to be a controlling factor, they may contribute to the overall product safety.

The [ACMSF report on vacuum and modified atmosphere packaging and associated processes](#) states specifically for nitrite that “inhibition of *C. botulinum* by nitrite in foods depends heavily upon a number of factors such as acidity and salt content. In addition, there are pressures to reduce nitrite levels in some foods because of the risk of formation of carcinogenic N-nitroso compounds in some situations. Taken together these two limitations mean that the scope for the use of nitrite on its own to control *C. botulinum* is limited”. Another issue surrounding the use of nitrite as a controlling factor is that nitrite depletes readily from the product during storage, thereby reducing the antimicrobial affect.

In summary, nitrite and other preservatives may have antibotulinal properties in a number of different food stuffs. However, as the efficacy of these preservatives seems to be dependent on the heat treatment given, the pH of the product and other constituents of the food, their use as controlling factors to prevent growth of nonproteolytic *C. botulinum* and toxin production needs to be evaluated for each specific product, for example by challenge testing or other appropriate means of validation. An FBO’s HACCP-based food safety management procedures should have ongoing monitoring to ensure that the products are of the right specification, which can control growth of non-proteolytic *C. botulinum* and production of toxin. The FBO must be able to demonstrate to the satisfaction of the Competent Authority both that the controlling factors are effective and also that the level of monitoring to ensure consistent adherence to specification is appropriate.”

39.Q: Could you investigate to ensure the vac pack equipment providers are giving the correct message to their customers as from what we can see they are just claiming their machines give extended shelf life “under refrigeration” which may be misleading?

A: It is up to FBOs to ensure that the food they produce is safe, so the onus is on them to clarify with their equipment providers the efficacy of the vac pack equipment. Question 10 of VP/MAP guidance refers. There is also a responsibility on FBOs to verify and validate their HACCP plans to ensure that control steps and the process is able to achieve safe food – if they cannot be sure that equipment is effective then it shouldn't be used.

40. Q: How can businesses deal with a possible menu conflict with maturation dates if their meat supplied now has a shorter shelf life and hence shorter maturation date? Could there be an interim enforcement exemption for businesses till the next change of menu or until primal suppliers review their original shelf life?

A: Answered in the Q&A (Q55) document for Food Information to Consumers document.

41. Q: Can food business operators rely on external accreditation bodies, such as BRC Grade A, to carry out checks on suppliers on their behalf regarding controls on *C. botulinum*?

A: Answered in the Q&A (Q55) document for Food Information to Consumers document.

42. Q: What are the rules for shelf-life on trimmings for mince and burgers?

A: Answered in the Q&A (Q55) document for Food Information to Consumers document.

43. Q: Would the supplier be required to validate the application of a shelf life of over 10 days on vac packed products supplied to catering butchers, if the product has been kept at less than 3°C at all times? The guidance on *C. botulinum* as updated in December 2020 no longer applies to VP/MAP chilled fresh beef, lamb and pork as described above.)

A: Yes. FBOs who place their products on the market must ensure that they are safe during the intended shelf life. Their HACCP documentation should specify the relevant control measure(s) to ensure safety within the allocated shelf life. FBOs should be able to provide scientific evidence that supports the shelf-life determination applied to their products. FBOs can consult experts (e.g. research organisations) on

how to establish and validate the shelf-life.

Although non-proteolytic *Clostridium botulinum* is not able to grow on foods stored at less than 3°C, FBOs must still take into account other hazards that might be associated with their products and which are capable of growing at temperatures below 3°C and controls for which should be included in HACCP based procedures, as well as taken into consideration when setting shelf-life. For example, the growth of non-pathogenic bacteria can result in spoilage that would make food unfit for human consumption and need to be considered.

However, if the shelf life determination is based on product being stored below 3 °C and the storage conditions confirming this are clearly set in the label or in other documentation passed on to other food businesses, then the supplier may not need to include the validation of the shelf life against non-proteolytic *C. botulinum* as this would not grow or produce toxin at the required storage temperatures.

44. Q: After opening and cutting of a vac packed product, would an FBO be required to apply a maximum of 10 days on the product if a storage temperature of less than 3°C cannot be guaranteed during processing/delivery to customers? Is it correct that the newly applied shelf life should not exceed the original supplier's shelf life?

A: FBOs should be able to provide scientific evidence that supports the shelf-life determination applied to their products. If the product is vacuum packed, the new shelf-life must not exceed the original shelf life applied on the product unless additional control measures are applied before the product is re-wrapped. The FBO needs to ensure adequate controlling factors are in place before applying a re-wrapped shelf-life of greater than 10 days. Q&A 24 to the guidance provides additional information.

45. Q: Are bacon and gammon (cured) products exempt from the 10 days shelf life ruling because of the salt/nitrite content?

A: Controlling factors need to be in place to prevent the growth of non-proteolytic *C. botulinum* if a shelf life longer than 10 days, at storage temperatures above 3 °C, is to be applied.

Salt is one of the controlling factors that can be applied in addition to chilled storage to extend the shelf life of vac packed meat beyond 10 days. There should be a minimum

salt level of 3.5% in the aqueous phase throughout the food. In complex foods this should be through all components of the food. Further information is in paragraph 37 of the safety and shelf-life of vacuum packed and modified atmosphere packed chilled foods guidance.

46.Q: Can mathematical modelling or challenge testing conducted at an industry level be used to demonstrate that individual businesses have conducted a sufficient risk assessment.

A: As set out in paragraphs 40 to 43 of the FSA/FSS guidance on vacuum pack and MAP as regards *C. botulinum*, mathematical modelling and challenge testing are approaches that can be taken to assess the potential for *C. botulinum* to grow and produce botulinum toxin in vacuum packed and MAP products.

Where food businesses wish to collaborate, each FBO needs to validate that the characteristics of their products and processes are comparable to the ones examined in these approaches (for example allow a safety margin, compared to the latter) and thus growth and/or toxin production data generated through these approaches are applicable to their own product and process. Caution should be taken if extrapolating environmental parameters.

With the provisos set out below FBOs may collaborate in conducting on mathematical modelling and/or challenge testing studies, either between different sites within the same company or different companies, e.g. through a trade association.

The FBO should be able to demonstrate to an enforcement officer that the characteristics of their products and processes are comparable to the ones examined in these studies. For example:

For these studies to be applicable to a given product, that product should have the same characteristics (i.e. pH, a_w , salt content, concentration of preservatives, atmosphere in the packaging, associated microflora or any other characteristic which may affect the growth of *C. botulinum* and toxin production), and;

The production process and storage conditions of the products should be similar.

The wrapping/packaging materials should be similar.

Different production areas may have different potential for contamination; however, products may have the same potential to support the growth of *C. botulinum* and

production of botulinum toxin.

If the products are not similar, the FBO should be able to show how they are different and what effect those differences have on their potential to support the growth of *C. botulinum* and production of botulinum toxin.