COMMENTS ON JUNE 2016 VP/MAP DRAFT REVISED GUIDANCE

These comments reflect the joint views of the Chilled Food Association, Institute of Food Research, British Meat Processors Association, Provision Trade Federation, Seafish, National Federation of Meat & Food Traders, National Association of Catering Butchers and the International Meat Trade Association on the draft revision to the existing FSA guidance issued for consultation at the end of June.

It should also be noted that the guidance is frequently applied by UK industry to all chilled prepared foods; therefore the title should reflect this or alternatively the document should make it clear that the guidance should not be applied other than to vacuum packed/MAP foods.

EXECUTIVE SUMMARY

We believe that the changes proposed go beyond routine updating and clarification and give rise to a number of concerns, notably in relation to:

- Challenge testing
- Use of “time to growth” in place of “time to toxin production”
- Packing conditions for non heat-treated food

We also feel that the section on re-wrapping is confusing and that the document as a whole tends to overstate the potential for problems with *C. botulinum*.

In the light of this, we would ask that:

- the revision exercise be put on hold pending a more substantive technical review in which the scientific evidence base for change can be properly evaluated and further work to establish an accepted challenge test protocol, and
- a full impact assessment is carried out as part of any future review.

We would be very happy to assist with this, either through the reconvening of a working group similar to that which developed the original guidance on the basis of ACMSF advice, or in the context of a new ACMSF report.

DETAILED COMMENTS

A. Challenge Testing

We do not accept the assertion that challenge testing measuring a demonstrable increase in viable count is preferred to testing for toxin. As botulinum toxin is the identified hazard, not the presence or quantity of the bacterium *per se*, it is imperative that botulinum toxin is measured. It has been shown in the scientific literature that *C. botulinum* toxin formation can occur in the absence of microbial growth (e.g. Kindler *et al.,* 1955[1]). It is also possible that some challenge organisms may die in the test sample whilst others multiply. While it is true that growth provides evidence of metabolic activity and thus an increased likelihood that toxin could be formed, failure to measure an increase in cell number does not prove that toxin has not been formed. Viable counts only show the number of cells alive at the time of testing and this does not necessarily echo historic toxin production. The presence of toxin without an increase in cell numbers has been observed in challenge studies where both have been measured, for example Brown & Gaze (1990)[2], Brown *et al.* (1991)[3], Hyytia *et al.* (1999)[4].

Direct measurement of *C. botulinum* in foods is difficult as there is not a culture medium that is specific for *C. botulinum*. Isolation uses non-selective nutritive media, often with the addition of egg yolk which can be used to identify lipase positive species such as *C. botulinum*. Selective media have been described for improved isolation of Group I strains: *C. botulinum* isolation agar (CBI) and botulinum selective medium (BSM) contain cycloserine, sulfamethoxazole and trimethoprim. These inhibitory agents help suppress overgrowth by competitive flora but also suppress growth of Group II strains and other non-toxigenic Clostridia species may grow on these media with similar morphological characteristics to *C. botulinum*. Lack of a specific agent means that foods require a high initial inoculum as the *C. botulinum* count must be larger than that expected from the natural flora.

The severity of the botulinum hazard means that any growth is unacceptable. This creates additional difficulty when determining the end point for challenge testing and setting pass/fail criteria.

The vast majority of *C. botulinum* challenge tests on foods have used toxin as the end point. For example, data on challenge tests collected for FSA report B13006 (Peck et al, 2006[5]) show 1193 out of 1238 challenge tests had been conducted by measuring toxin and only 45 measured growth. The statement that testing for evidence of growth is preferred to testing for toxin represents a major change in current advice and requires detailed justification.

Overall, the text proposed on page 15/16 regarding challenge testing is very dangerous and may lead to botulism outbreaks. As noted earlier, since botulinum toxin is the hazard, not the bacterium *per se*, it is imperative that botulinum toxin is measured and not microbial growth. It should be noted that there are reports in the scientific literature of toxin formation in the absence of microbial growth, thus the absence of growth may give a completely incorrect impression of a safe product. Thus, paragraph 27 must state “will not form botulinum neurotoxin” rather than “will not grow”. Paragraph 28 must

[1] Kindler S.H., Mager J. and Grossowicz N. (1955). Production of toxin by resting cells of *Cl. parabotulinum* type A. Science 122(3176): 926-927.

[2] Brown G.D. and Gaze J.E. (1990). Determination of the growth potential of *Clostridium botulinum* types E, and non-proteolytic B in sous vide products at low temperatures. Camden Food and Drink Research Association Technical memorandum No.593.

[3] Brown G.D., Gaze J.E. and Gaskell D.E. (1991).Growth of Clostridium botulinum non-proteolytic types B and E in “sous vide” products stored at 2-15°C. Camden Food and Drink Research Association report on MAFF project 7050A.

[4] Hyytia E., Hielm S., Mokkila M., Kinnunen A. and Korkeala H. (1999). Predicted and observed growth and toxigenesis by *Clostridium botulinum* type E in vacuum-packaged fishery product challenge tests. International Journal of Food Microbiology 47: 161-169.

[5] Peck M.W., Goodburn K.E., Betts R.P. and S.C. Stringer (2006) *Clostridium botulinum* in vacuum packed (VP) and modified atmosphere packed (MAP) chilled Foods. Final report on FSA project (B13006). http://www.ifr.ac.uk/safety/Final_project_report0707.pdf

state “shows any evidence of toxin formation” rather than “shows any evidence of growth”. Paragraph 29 must read “capable of producing toxin” not “capable of growing and producing growth”.

- Para 28 (page 15) appears to limit shelf life to 10 days if a challenge test is carried out and growth occurs, irrespective of how long the test has run for. For example if growth were to occur on day 25 then why should the shelf life be limited to 10 days as written? Likewise, on page 16, paragraph 28, what happens if the challenge test reveals that there is toxin formation/growth in less than 10 days?

- On page 16 a new paragraph is required immediately after the section on challenge testing on alternative approaches. It needs to mention that there are alternative approaches to predictive modelling and challenge testing. One of these is to demonstrate that the food is safe through the implementation of a process risk model using risk assessment techniques. This work will need to be carried out by an appropriate centre of expertise.

- In para 14 (page 8) in addition to challenge testing other approaches should be included such as predictive modelling (note: ComBase does not use heated spores so is failsafe), risk assessment, process risk modelling, Quantitative Microbiological Risk Assessment (e.g. as carried out in the SUSSLE (Sustainable Shelf Life Extension) projects).

- Question 2 (page 17): The answer must state “will not form toxin” not “will not grow”.

- Question 6 (page 19): We agree with the principles given here but there should be a new final sentence such as “The actual spore loading could be taken account of using a process risk model approach. This work will need to be carried out by an appropriate centre of expertise”.

- Question 7 (page 19): This should be revised to “it would be acceptable for challenge testing to be carried out or an alternative approach used to determine whether”. Also request revision to “Challenge test or an alternative approach should be carried out by”.

- Question 8 (page 21): Should be revised to “this may be done by predictive modelling or challenge testing or an alternative approach as detailed elsewhere in the document”.

- Question 9 (page 21): The document is completely wrong to state that testing for growth is the preferred approach rather than testing for toxin formation, and the statements in this paragraph are highly dangerous and may directly lead to outbreaks of foodborne botulism. This is because (1) botulinum toxin is the hazard, not the bacteria *per se*, and (2) there are reports in the scientific literature of toxin formation in the absence of microbial growth. Thus the absence of growth in a challenge test may give a completely incorrect impression of a safe product and lead to foodborne botulism outbreaks. This paragraph needs to be completely rewritten. All references about “testing for growth” elsewhere in the document must be changed to “testing for toxin”.

B. 'Aseptic Conditions'

1. **Basis for claims that 'spores are widely distributed in the environment and are liable to be present in food'** (page 7, point 11 and page 11, point 17)

   The LINK-funded SUSSLE (Sustainable Shelf Life Extension) project AFM266 quantified spores in a wide range of foodstuffs and demonstrated that this was not the case. See Barker *et al* "Quantification of non-proteolytic *Clostridium botulinum* spore loads in food materials", http://aem.asm.org/content/early/2016/01/04/AEM.03630-15.

2. **Lack of Risk Assessment and scientific evidence that open products are being contaminated in High Risk Areas by spores in the environment** (page 13, point 13)

   In the decision tree (page 10) 'Is the wrapping done' box reference to 'e.g. High Risk Area' would be more appropriate than 'e.g. aseptic conditions' given it is a long-established and demonstrably effective best practice approach over several decades:

   - A **High Risk Area (HRA)** is an area designed to a high standard of hygiene where practices relating to personnel, ingredients, equipment and environment are managed to minimise microbiological contamination of a ready-to-eat or ready-to reheat product comprising only cooked ingredients (i.e. having attained a minimum of heat process to control relevant pathogens, e.g. *L. monocytogenes* (minimum 70°C/2 mins equivalent for 10 days maximum shelf life), non-proteolytic *Cl. botulinum* (minimum 90°C/10 mins equivalent).

   There is no evidence of which we are aware that non-proteolytic *Clostridium botulinum* spores are floating free in the air in a High Risk Area factory environment, for example. Air intake into a HRA is filtered to a high standard and no outdoor clothing or raw foods are present in such an area.

   In any case, aerial/aerosol transfer of botulinum toxin from one food to another should not be an issue, since there should be no toxin present in a food producing environment, toxin production requiring anaerobic conditions. According to HPA (now Public Health England, PHE)[6] "Inhalation botulism does not occur naturally". Spore transfer via aerosol is not considered to be a significant risk in a food production environment. Spores sufficient to present a hazard are highly unlikely to be present in a food manufacturing environment. Similarly, according to HPA, spores transferred in water "will only pose a risk to humans in some deliberate release scenarios because the toxin is inactivated by normal treatment of mains water supplies. There have been no reported cases of illness in humans worldwide due to contaminated water supplies." From this together with the SUSSLE projects' data on spore loadings, aerosolisation or in water is not a significant risk.

   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. Foegeding and Busta[7] found that *C. botulinum* spores were sublethally damaged by 2 minutes exposure at 25°C and pH7 to 2.7 x 10^{-6} to 3.1 x 10^{-6} grammes of available chlorine per spore.

[6] Guidelines for Action in the Event of a Deliberate Release: Botulism, HPA (31/3/09), v 4.5.1. http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947315628

[7] Hypochlorite Injury of C. botulinum 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

Ito and Seeger[8] reported times of 5.5-7.0 min for 3 log reduction in spores of non-proteolytic C. botulinum (3 strains tested, one each of types B, E and F) in the presence of 4.5 ppm free chlorine in phosphate buffer, at 25°C.

Ito *et al*[9] reported time for 4 log decrease in type E spores (Saratoga strain) of 4 minutes at pH 6.5 in phosphate buffer in the presence of 4ppm $Ca(OCl)_2$ at 25°C.

Duo-pasteurisation approaches used on the Continent for many decades make use of High Risk Area controls by utilising 90°C/10 mins followed by packing in a High Risk Area, then post-pack pasteurising (70°C/2 mins) to control vegetative organisms to give a chilled life of 6 weeks.

3. **Medical evidence to show that non-proteolytic *Cl. botulinum* food poisoning is an issue in the general population**

The UK's chilled food industry has produced an estimated $2x10^{10}$ 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 being up to 10 days. Similar numbers of VP/MAP raw and cooked protein have also been produced in the UK over that time period, again without *Clostridium botulinum* 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. An extensive review was commissioned by FSA (B13006) which demonstrated this. See "*Clostridium botulinum* in vacuum packed (VP) and modified atmosphere packed (MAP) chilled foods, July 2006" (www.ifr.ac.uk/safety/Final_project_report0707.pdf), also published in Trends in Food Science & Technology 19(4):207-216, April 2008.

C. Re-Wrapping

In the decision tree (page 10) the use of the term 'wrapping' inadvertently brings into the scope bulk cheese blocks that are vacuum packed and matured without a shelf life at 8-12°C and subsequently cut into smaller blocks that are MAP. As the document stands, this longstanding standard system would be impacted for no scientific reason. Stipulating the 3-8°C temperature range in the title of the decision tree would exclude from the scope both this system and that of maturing meat at ≤3°C under VP from the scope, both of which are technically sound approaches.

We would propose for clarity that the following sentence be included in the guidance in the questions and elsewhere stating that "***The original shelf life of a product should not be extended or restarted following rewrapping***."

D. Additional Issues

In addition to resolving the above points so they reflect scientific evidence and best practice, we suggest:

[8] Effects of germicides on microorganisms in can cooling waters, Ito, K.A., Seeger, M.L., J Fd Prot, 1980, 43 (6), p. 484-7
[9] The Thermal and chlorine resistance of *Cl, botulinum* types A, B and E spores, in Botulism (Eds Ingram, M., Roberts, T.A.), London, UK: Chapman and Hall, p.108-22.

- The title of the decision tree on page 10 should refer to 3-8°C as scientific evidence relates to this temperature range.

- In the decision tree (page 10) 'does a single controlling factor' box reference to 'e.g. challenge tested' would be more appropriately replaced with text referring to alternative methods of assessment as there is over-reliance on challenge testing generally in the document.

- The 'Controlling Factors' box at the base of the decision tree on page 10 refers to the wrong paragraph in the text – it should be para 25 on pp14-15 and/or Q8/A8 on page 20, not para 13.

- Clarification of wording is needed regarding the non-applicability of the guidance where food is stored <3°C owing to lack of growth of non-proteolytic *C. botulinum*, e.g. in the penultimate para of the summary/purpose and in the answer to Q5. This lack of clarity comes up repeatedly in dialogue with EHOs.

- Deletion from para 12 (page 7) of "It is important to note that the presence of air, or a similar oxygen-containing atmosphere, cannot be relied upon as the sole control to prevent growth and toxin formation by non-proteolytic *C. botulinum*" as it cannot be used in combination with other factors either. Request replacement with text stating that a risk is presented by non-proteolytic *C. botulinum* in low oxygen or MAP foods, "Thus, the risk presented by non-proteolytic *C. botulinum* should be considered the same in foods packed under air as under VP/MAP".

- The inclusion on page 8 of the requirement to consider *L. monocytogenes* when setting shelf life is a step forward. However, the control and potential growth of all other relevant pathogens needs also to be taken in to consideration, i.e. those that might survive but not grow in correctly stored chilled food such as Salmonella, STEC/VTEC. Should the document give more information on controlling these?

- Table 1 (page 12) reproduces the previous edition's lethal rates table although the lethal rates given for <90°C are less protective than those required by industry in long-established guidance (CFA and European Chilled Food Federation), and which have been shown to be appropriate in PhD work funded recently by FSA at IFR. The recently published peer-reviewed paper by Wachnicka (Applied Environmental Microbiology 2016, http://aem.asm.org/content/early/2016/07/25/AEM.01737-16.abstract) summarises this work and confirms that the CFA (and European Chilled Food Federation) guidelines for equivalent to 90°C/10 minutes provide for greater safety assurance at less than 90°C than those given in the guidance. The lethal rates given therefore need to be replaced with those already in use by industry to better protect the consumer. The table in the guidance also takes no account of the potential effects of lysozyme. There would be benefit in including text that states that higher heat treatment are likely to be necessary if the food contains lysozyme.

- Para 25 (page 14) and Q8 answer (page 20): The proposed guidance mentions that preservatives such as nitrite, sorbic acid, benzoate and lactate can be used as controlling factors. These are not permitted treatments for a number of products (such as most processed seafoods), the use of which is covered by legislation covering additives, most importantly Regulation EC No 1333/2008.

- In para 14 and elsewhere (para 26) we request amending 'research associations' to 'research organisations'. Universities and institutes are valuable sources of information.

- The last line of para 14 should read “(e.g. modelling, challenge testing)”.

- Q4 answer (page 18): ‘ought’ should be changed to ‘must’.

- Q8 answer (page 20): The proposed guidance mentions that preservatives such as nitrite, sorbic acid, benzoate and lactate can be used as controlling factors. These are not permitted treatments for a number of products (such as most processed seafoods), the use of which is covered by legislation covering additives, most importantly Regulation EC No 1333/2008.

- Q14 answer (pp 22-23) should refer to verification. The document currently confuses validation (ensuring that an appropriate safe process is identified) and verification (ensuring that a valid process is correctly applied).