

Guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to *Clostridium botulinum*

5th Meeting of the FSA VP/MAP Guidance drafting group, Thursday 27th September, 2007, Room 531, AVH

Present

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| Alec Kyriakides (AK) | BRC |
| Kaarin Goodburn (KG) | CFA |
| Mike Peck (MP) | IFR |
| Mike Stringer (MS) | CCFRA |
| Roy Betts (RB) | CCFRA |
| Jenny Morris (JM) | CIEH |
| Kathryn Callaghan (KC) (Chair) | FSA, MSD |
| Ian Smith (IS) | FSA, MSD |

Apologies

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| Maurizio Rossi (MR) | Sealed Air |
| Kevin Woodfine (KW) | FSA |
| Paul Cook (PC) | FSA |

Chair's introduction

1. The Chair welcomed members to the 5th meeting of the drafting group, convened to consider the responses from the limited consultation' which closed in early September. Dr Roy Betts of CCFRA was welcomed to the meeting, attending for agenda item 1.

Minutes of the previous meeting.

2. MP proposed changes to paragraph 6 with respect to the use of combined Z values from the ACMSF report and CFA guidance, to cover the temp range 80°C to 100°C. Revised paragraph 6 now reads

"The Lethal Rate table was discussed at length. Agreed that the 'Lethal Rate' column should be deleted. The table includes Z values based on ACMSF and CFA data. Concern was expressed over the use of ACMSF Z values below 80°C. The data included in table 1 are therefore limited to the 80°C to 90°C range. The CFA document includes Z values between 90°C and 100°C. Therefore, by combining the two the table covers the temp range 80°C - 100°C using the two corresponding Z values. A definition of Z value will be included in the glossary. A footnote on the use of two Z values will be added. The table will be re-drafted and circulated to the drafting group for comment."

The changes to the minutes were agreed by members. It was agreed by the drafting group that the full set of minutes could be published on the Agency's website in due course. Publication in the public domain satisfies the need for a full Regulatory Impact Assessment with respect to the guidance and this approach has been agreed by senior Agency colleagues.

Responses to the 'limited-consultation' comments received from Dr Roy Betts, Head of Microbiology, CCFRA.

3. RB presented his proposed changes to the guidance:
 - Agreed that the Title should cover what the guidance attempts to do rather than the intended audience. The title should indicate that coverage does not include all chilled foods but those which are VP or MAP packaged. i.e. 'Food Standards Agency guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*'.
 - Paragraph 2, it was agreed that the chill temperature controlling factor should be in the range $3^{\circ}\text{C} \leq 8^{\circ}\text{C}$. The maximum lower limit of growth of *C. botulinum* was discussed. Previous industry guidance and the ACMSF report states that control occurs at 3°C . Scientific evidence suggests that in growth media *C. botulinum* will grow and produce toxin in ~ 5 weeks at 3°C . However not aware of any studies using food matrices. Agreed that growth will occur at 3°C and even 0.1°C increments at the limit of *C. botulinum* growth can have a significant effect on time to toxin production. Temperature control by industry is outside of any tolerance set around 3°C . The guidance is intended to be based on existing industry guides, therefore it is not appropriate to give new advice which has not been endorsed by the ACMSF. Suggested wording on temp control to clearly state that growth occurs above 3°C , but not below it i.e. Para 3 to read 'The microbiological safety concerns summarised here will be restricted to the control of non-proteolytic *C. botulinum*, which is able to grow and produce toxin above 3°C . At less than 3°C growth of non-proteolytic *C. botulinum* does not occur'.
 - Delete reference to high and medium risk foods and Table 1. Should be clear that the guidance is intended for all ready to eat and raw foods. The group warned that low risk foods can present significant risk for *C. botulinum* if controlling factors are not applied correctly. Table 1 should be replaced by a new reduced table based on a few examples from table 1, it should give a steer for the priority for attention.
 - Paragraph 10, Revise wording for foods in air or oxygen containing atmospheres. MP to consider.

Action Point MP to give further examples of foods packaged in air which could support *C. botulinum* growth, under certain conditions.

- RB considered that table 1 should be deleted. The ranking of food categories in column 4 could imply that certain foods were not a significant risk i.e. low inherent risk for *C. botulinum*, yet in practice this risk ranking was more based on well established controlling factors and manufacturing practices. JM and AK considered that prioritising of food types was a pragmatic approach likely to be adopted by EHOs. It was agreed that the existing table was confusing particularly for medium risk foods such as fresh chilled pasta which could be inherently very dangerous with respect to *C. botulinum*. The drafting group agreed that the table should be revised to include just three examples, one from each priority for attention category i.e. high, medium and low risk for *C. botulinum*. This will help EHOs adopt an informed proportionate approach to enforcement when considering imminent risk to the consumer. The revised and simplified table will be moved to the Q&A section.

Action Point IS to produce new simplified table.

- Agreed that paragraph 10 on home vac packing should be deleted. The guidance is not aimed at the consumer and this recommendation is unenforceable.
- The Decision Tree was considered. Envisaged that this is the key part of the guidance and is likely to be used as a stand alone reference by food business operators. Therefore will include the control factors for *C. botulinum* for reference. i.e. Heat Treatment, Acidity of the food, Sodium Chloride content, Water activity, Others e.g. nitrite.
- The text box for 'Re-Wrapping' was revised as per RB suggested changes, now reads 'If a VP/MAP product is unwrapped, e.g. for slicing or portioning, and then rewrapped, the shelf life given to the re-wrapped product must not exceed the shelf life given to the original product. Where the re-wrapped shelf life is to be greater than 10 days then this must be justified with respect to controlling factors with respect to non-proteolytic *C.botulinum*'.
- The text box for VP/MAP Ingredients was revised following discussion on the need for the shelf-life of component ingredients to be factored into the shelf-life of the final product, unless an 'in pack' heat treatment is given i.e. 70°C for 2 minutes. Now reads 'Where VP/MAP ingredients are used in another product the life of the final product shall not exceed that of the original lives given to the ingredients. However if the product is given a further heat treatment to destroy vegetative cells, e.g. 70°C for 2 minutes, the shelf-lives do not need to be incorporated into that of the final product providing the HACCP plan demonstrates that it remains fit for consumption'.

- Members agreed that the decision tree should indicate that below 3°C the growth of *C. botulinum* is controlled indefinitely. However, the issue of growth of *C. botulinum* at 3.0°C was discussed. The existing ACMSF advice gives 3°C as the lower limit of growth. Scientific evidence which has not been considered by the ACMSF, suggests that growth of *C. botulinum* does occur at 3°C. Therefore, rather than stating storage at $\leq 3^\circ\text{C}$ as a controlling factor for *C. botulinum*, it was agreed that the title of the decision tree should read 'Determining the Shelf-life of VP/MAP Products stored above 3°C'. this implies that growth does not occur below 3°C with out referring to the limit of actual growth of *C. botulinum* and remaining consistent with current ACMSF advice.
- It was agreed that the controlling factors for *C. botulinum* should appear earlier in the guidance i.e. before the decision tree and should be listed in a similar format to page 18 of the ACMSF report on VP and Associated Processes.
- The paragraph on heat treatment as a controlling factor was revised to read 'If heat treatment is to be used as the single control factor, the minimum heat treatment required to manufacture a chilled VP/MAP product is 90°C for 10 min or equivalent achieved at the slowest heating point in the product'. Equivalent times and temperatures are given in Table 2'. The use of the term protection factor was discussed wrt a 6 log reduction. Evidence suggests that growth does occur after 40 days following 90°C for 10 min, suggesting that a 6 log reduction may not be achieved. Members did agree that it would be unreasonable to give a restrictive shelf-life following a 90°C for 10 min heat treatment if the initial spore loading was low. Clearly there is risk factor beyond 40 days but this is dependent on the initial spore loading. It was thought that only the largest and most sophisticated manufactures would base long shelf lives on the use of protection factors in this manner.
- The salt calculation equation was confirmed as being correct
- The drafting group discussed the relative effectiveness of salts and sugars to control water activity. Thought that other solutes may be slightly less effective than NaCl in controlling growth of *C. botulinum* at a specific water activity. Thought to be insufficient evidence on the relative effectiveness of sugars with respect to salts in controlling *C. botulinum*.
- Although the previous ACMSF guidance does not recommend a particular predictive model the consensus of the drafting group was that Combase Predictor should be recommended. This would prevent the use of less satisfactory models which may be unsafe without informed interpretation of the parameters being used. Members sought the Agency's view on the use of predictive models without supporting evidence from challenge testing.

Action point FSA to consider and advise on the use of Predictive Modelling without the need for supporting evidence from challenge testing.

- Agreed that a definition of Challenge Testing should be included in the glossary. This would be the definition used in the CFA industry guide.
- Paragraph 9 on the practice of re-wrapping should be changed to be consistent with the Re-Wrapping text box of the decision tree.
- Agreed that question 2 of the Local Authority Section should be changed to 'How should a food business establish the appropriate shelf life with respect to non-proteolytic *C. botulinum* for its products?'

Discussion of comments received from Meat & Livestock Commission.

4. The drafting group did not agree with the statement that 'It seems unlikely that the high oxygen atmospheres.....would support toxin formation'. Paragraph 10 on the risk of *C. botulinum* growth in oxygen atmosphere packaging should remain. It was agreed that MP would provide further examples of foods in high oxygen environments, which have supported growth of *C. botulinum*.

Action point MP to provide further examples of foods packed in high oxygen environments which have been documented as supporting growth of non-proteolytic *C. botulinum*.

5. Members agreed with MLC and BMPA comments that storage at <3°C is not covered by the guidance and a line will be added to reflect that.

Discussion of comments received from LACORS

6. The drafting group did not agree with LACORS's comments with respect to the answer to Question 13. The Local Authority *should* take steps to gather suitable evidence unless there is an imminent risk to public health such as failure of controlling factors in a high risk food category, or the HACCP plan does not include controlling factors for a shelf life of greater than 10 days.

Clarification on start of shelf life for VP foods

7. The drafting group considered this point and advised that the shelf life begins after the controlling factor(s) have been first applied, or if a botulinum cook is being applied, shelf life begins from the point of cooking. This will be added to the guidance.

Timetable

8. The guidance will now be presented at the December ACMSF meeting. Members suggested that the guidance should be reviewed by ACMSF members with expertise in this area, prior to the December meeting. KC will discuss options with the ACMSF secretariat.

A.O.B.

9. There were none

Date of next meeting

10. To be advised if required.