Recommendations

In this guide

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- 1. Report on Botulinum Neurotoxin-Producing Clostridia
- 2. <u>Taxonomy of Botulinum Neurotoxin-Forming Clostridia and their Neurotoxins</u>
- 3. Detection
- 4. Epidemiology
- 5. Occurrence, Growth and Survival
- 6. <u>Risk Assessment</u>
- 7. <u>Recommendations</u>
- 8. <u>References</u>

(1) Foods should continue to be formulated to control *C. botulinum* and other botulinum neurotoxin-producing clostridia in accordance with the known factors (described in this report). With regard to these controls, actions recommended to the FSA are;

- At the first opportunity replace in their guidelines the current statement "a combination of heat and preservative factors which can be shown consistently to prevent growth and toxin production by non-proteolytic *C. botulinum*" with a modified statement "a combination of controlling factors which can be shown consistently to prevent growth and toxin production by non-proteolytic *C. botulinum*"
- At the first opportunity make explicit in their guidelines that z = 7 and z = 10 centigrade degrees should be used to evaluate equivalent thermal processes for operating temperatures below and above the 90°C reference temperature respectively
- At the first opportunity make explicit that all studies relating to controlling factors for *C. botulinum* should determine neurotoxin production with potential merit in also monitoring growth
- Emphasise that other controlling factors, including herbs and spices, bacteriocins, phosphates, citrates, sorbates, sulphites, etc., can be highly

variable in delivering consistent and reliable control of *C. botulinum*, and other botulinum neurotoxin-producing clostridia, and ensure that food business operators relying on such controls must provide evidence to demonstrate initial efficacy of the factors used for controlling these organisms in their foods together with ongoing control and measurement

• Emphasise that nitrites, in combination with other controlling factors, exert an important anti-*C. botulinum* effect, which is difficult to predict due to the complexity of the chemical pathway leading to inhibition of growth and toxin formation, and therefore provide guidelines that ensure other preservation factors are adjusted if nitrite concentration is to be reduced in, or removed from, foods traditionally containing it where there is a significant history of safety with respect to *C. botulinum*.

(2) The evidence does not facilitate revision of the current reference process, heating at 90°C for 10 minutes or an equivalent, but there is strong evidence that this process provides a lethality that exceeds the target 6 order of magnitude reduction in population size that is widely attributed to the reference process. The subgroup recommends that the FSA should consider any evidence, from food business operators, indicating the value of further investigations that could address this issue.

(3) Early detection of cases and rapid, effective coordinated responses to very rare incidents are identified as crucial elements for reducing risks from foodborne botulism. It is recommended that the FSA work closely with other agencies to establish clear and validated preparedness in relation to potential major incidents of foodborne botulism in the UK; this may involve methods to increase awareness of cases presenting for healthcare, transparent methods for epidemiological linkage of cases, rapid accessibility to sufficient high quality laboratory capacity, capability to identify botulism from organisms other than *C. botulinum* and established pipelines for monitoring rapid alerts in other locations.

(4) Temperature abuse has been highlighted as the cause of the majority of incidents relating to botulism in chilled foods. It is recommended that the FSA highlight the importance of temperature control in consumer food hygiene campaigns, together with adherence to recommended Use By dates, to reinforce these critical consumer food safety controls.

(5) It is recommended that the FSA works with other organisations to ensure that, whenever possible, the causative organism that is isolated from foods, cases or outbreaks of botulism is fully characterised to determine its phenotype for use in risk assessments.

(6) Evidence includes relatively few incidents involving chilled foods that identify non-proteolytic *C. botulinum* as the causal organism of botulism and no incidents or outbreaks implicating chilled foods where the food has been stored under the recommended chilled conditions and consumed within its stated shelf life have been reported. It is recommended that the FSA considers commissioning a review of controls used in other countries, for non-proteolytic *C. botulinum* in foods, to determine whether a subsequent exposure assessment should be undertaken for vacuum or modified atmosphere packed chilled foods in the UK.

(7) Emerging information confirms that other clostridia, including *C. sporogenes*, *C. butyricum* and *C. baratii* contribute to foodborne botulism, and may present discrete risks, and it is recommended that the FSA routinely include specific consideration of these organisms, in any plans that are developed to maintain the safety of food, with regard to foodborne botulism. Where practical it is recommended that the FSA identify and support research studies conducted to establish the boundaries for toxin production (and possibly also growth where appropriate), for neurotoxigenic *C. sporogenes, C. butyricum* and *C. baratii* under otherwise optimal conditions in foods.

(8) Evidence shows that *C. botulinum* can grow and produce toxin in foods where relatively high levels of oxygen or air are present and, whilst vacuum or modified atmosphere packaged foods are likely to provide more favourable conditions for *C. botulinum*, it is recommended that FSA initiate a dedicated consideration of botulism risks associated with non-vacuum or modified atmosphere packaged foods.

(9) WGS has provided improved understanding of the taxonomy and diversity of botulinum neurotoxin-forming clostridia, and their neurotoxins, and this has substantially improved the ability to track and trace outbreaks of human foodborne botulism. It is recommended that the FSA involve their academic partners and take a lead in the generation and coordination of molecular information relating to *C. botulinum* taxonomy.

(10) It is apparent that increased understanding of the genotypic and phenotypic homogeneity of distinct groups of botulinum neurotoxin-producing clostridia will contribute to improved assessment of human foodborne botulism risks. It is recommended that the FSA use academic partnerships to develop this knowledge.