

Supplement

Food Safety Objective Approach for Controlling *Clostridium botulinum* Growth and Toxin Production in Commercially Sterile Foods

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ABSTRACT

As existing technologies are refined and novel microbial inactivation technologies are developed, there is a growing need for a metric that can be used to judge equivalent levels of hazard control stringency to ensure food safety of commercially sterile foods. A food safety objective (FSO) is an output-oriented metric that designates the maximum level of a hazard (e.g., the pathogenic microorganisms or toxin) tolerated in a food at the end of the food supply chain at the moment of consumption without specifying by which measures the hazard level is controlled. Using a risk-based approach, when the total outcome of controlling initial levels (H_0), reducing levels (ΣR), and preventing an increase in levels (ΣI) is less than or equal to the target FSO, the product is considered safe. A cross-disciplinary international consortium of specialists from industry, academia, and government was organized with the objective of developing a document to illustrate the FSO approach for controlling *Clostridium botulinum* toxin in commercially sterile foods. This article outlines the general principles of an FSO risk management framework for controlling *C. botulinum* growth and toxin production in commercially sterile foods. Topics include historical approaches to establishing commercial sterility; a perspective on the establishment of an appropriate target FSO; a discussion of control of initial levels, reduction of levels, and prevention of an increase in levels of the hazard; and deterministic and stochastic examples that illustrate the impact that various control measure combinations have on the safety of well-established commercially sterile products and the ways in which variability at all levels of control can heavily influence estimates in the FSO risk management framework. This risk-based framework should encourage development of innovative technologies that result in microbial safety levels equivalent to those achieved with traditional processing methods.

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The minimum of a 12-log reduction of *Clostridium botulinum*, the basis for determining a safe process for thermally processed commercially sterile food, has not changed in more than 90 years, but processing technologies that could replace traditional thermal processes have developed rapidly in recent years. According to the Codex Alimentarius Commission (21), “‘Commercial sterility of thermally processed food’ means . . . to render the food free from microorganisms capable of growing in the food at normal non-refrigerated conditions at which the food is likely to be held during distribution and storage.” Often the treatment necessary to render a food product commercially sterile does not target a defined safety level but instead targets the prevention of spoilage when the food product is held under normal storage conditions. As a result, there is a great deal of variability among processes applied to

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