Thermally Processed,
Commercially Sterile Products

By

Paul Uhler, FSIS

Thermally processed, commercially sterile meat and poultry products are commonly referred to as canned products although the containers can be flexible, such as pouches, or semi-rigid, as in lunch bowls.

Thermally processed, commercially sterile products are addressed in two subparts of the current regulations. The two sections are identical except that Subpart G, 318.300 – 311, pertains to meat products and Subpart X, 381.300 to 311, pertains to poultry products. These regulations are either prescriptive, containing detailed requirements for containers and container closures, equipment specifications and operations, finished product inspection, product recall or overlap those of the HACCP – recordkeeping and record review, corrective actions in the event of a processing deviation, and implementation of validated process schedules.

Like processors of other RTE products, processors of thermally processed, commercially sterile meat and poultry products must address biological, physical, and chemical hazards when developing their HACCP plan. However, establishments do not have to address the food safety hazards associated with microbiological contamination if the product is produced according to the requirements in the meat or poultry canning regulations. This exception is contained in 417.2(b)(3) of the HACCP regulations. In permitting this exception, the Agency recognized that the canning regulations were "based on HACCP concepts and provide for the analysis of thermal processing systems and controls to exclude microbial hazards." However, the preamble stated that this exception would remain only until changes in the canning regulations, that is, performance standards, were finalized. Maintaining the prescriptive regulatory approach to a single category of meat and poultry products is inconsistent with FSIS' other regulatory initiatives to grant industry maximum flexibility to innovate in processing, while clarifying industry's responsibility and accountability for the safety of meat and poultry products. Moreover, while it may appear that the current exemption provides industry with the flexibility to either innovate or simply to address microbiological hazards through implementation of the current canning regulations, in reality their HACCP plans must still comply with the regulatory requirements. Therefore, the change to performance standards is not merely making the regulatory language consistent with that for other RTE products.

FSIS is proposing lethality performance standards to ensure elimination or control of the pathogen *Clostridium botulinum* in thermally processed, commercially sterile meat and poultry products. The performance standards are regulatory statements of current industry practice. FSIS also is proposing a revised requirement ensuring commercial sterility of these products. The remaining changes to the current regulations will be the removal of the prescriptive requirements of the current regulations and those requirements, such as

recordkeeping, that overlap the HACCP regulations. FSIS will retain the training requirement for supervisors. In other words, the proposed changes should not affect current industry practice.

The current processing objective for canned products is commercial sterility. However, commercial sterility addresses both food safety and non-food safety forms of contamination. Therefore, FSIS is proposing both different lethality performance standards, depending on whether the process is designed to kill the pathogen or prevent growth of the pathogen in the product, and a standard for commercial sterility. For example, in most low-acid products the thermal process is designed to eliminate the pathogen from the product. On the other hand, in acidified products, such as a spaghetti sauce, pathogen growth is controlled by acidification.

In the first performance standard, FSIS is proposing to require that an establishment's process for producing a low-acid canned product that receives a thermal, or other sporicidal process, result in a probability of 10^{-9} or less that there are spores of *C. botulinum* in a container of the product that are capable of growing, assuming an initial load of 1000 spores per container. Alternatively, the establishment may achieve a 12-$\log_{10}$ reduction of C. botulinum.

In the second performance standard, FSIS is proposing to require that the processing of acidified products and of some cured products and other canned products in which pathogen growth is controlled by factors other than the thermal process, prevent multiplication of C. botulinum. For these products, processing must prevent growth rather than achieve any specific decimal reduction of C. botulinum.

In addition to the performance standards, FSIS also is proposing a specific requirement that all thermally processed, commercially sterile products, in fact, be commercially sterile and hermetically sealed. This requirement is consistent with the existing shelf-stability/commercial sterility definitions in Sec. 318.300(u) and 381.300(u) of the USDA regulations and 21 CFR 113.3(e) of the FDA regulations for commercial sterility of canned products. A commercial sterility requirement is necessary to protect against both food-safety-related and non-food-safety-related forms of contamination. Product that has undergone more processing than necessary to protect health, but less than necessary for commercial sterility, is safe, but it may not be stable.

FSIS considers a commercial sterility standard to be appropriate, among other reasons, because the Agency is obligated under the statutes it enforces to administer programs aimed at preventing all forms of adulteration of meat and poultry products. The Agency's current thermal processing regulations are intended to ensure that canned and other thermally processed products are not adulterated.

The proposed commercial sterility requirement would mean that the process for a canned product, in addition to reducing or inactivating C. botulinum spores, would have to ensure a reduction or inactivation of spore-forming organisms sufficient to guarantee commercial sterility. A process that ensures a 10^{-9} probability of contamination by C.

botulinum spores will not provide the same probability of destruction of the most heat-resistant microorganisms, such as *Clostridium sporogenes*. FSIS is proposing a general and not a quantitative standard for commercial sterility in this document but requests comment on whether a quantitative standard is necessary. For example, a 5-log reduction of *Clostridium sporogenes* or a 10^{-6} probability of remaining spores.

Hermetic sealing of a container protects the product and prevents microorganisms or other potential contaminants from entering the container. If the container seal is inadequate, the product may no longer be microbiologically stable. C. botulinum or spoilage organisms could contaminate the product during container cooling or storage. The product could become adulterated because of spoilage, an economic concern, or because of C. botulinum, a public health concern. For this reason, FSIS considers appropriate, and is proposing, a hermetic sealing requirement. FSIS is proposing that the seal be airtight to protect the contents of the container from the entry of microorganisms.

FSIS also recognizes that commercial sterility could be achieved by other than a thermal process. Therefore, the definition of commercial sterility has been expanded to include those processes.

The proposed definition of commercial sterility is:

> The condition achieved by application of heat, irradiation, high-pressure, or other processes, alone or in combination with other ingredients or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50°F or 10°C) at which the product will be held during distribution and storage.

The commercial sterility requirement is:

> The product must be processed to achieve commercial sterility and the container in which the product is enclosed must be hermetically sealed so as to be airtight and to protect the contents of the container against entry of microorganisms during and after processing.

Several industry groups and other interested parties have expressed reservations concerning any replacement of the existing regulations for thermally processed, commercially sterile products with performance standards. The complexity of the canning process, as well as the virulence of *C. botulinum* toxin which can form in canned products, have been cited as reasons for maintaining the existing, prescriptive regulations. Significantly, FSIS is proposing to retain the requirement that all operators of processing systems for commercially sterile meat and poultry products and container closure technicians be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for training supervisors of canning operations.

The remaining changes are in the definitions. For acidified product, the term low-acid was dropped and the phrase "validated as safe" replaces demonstration by a processing authority that a longer interval is safe. For low acid product, the phrase "commercially sterile and hermetically sealed" replaces the word "canned."

FSIS specifically invites comment as to whether and in what form the existing requirements for thermally processed, commercially sterile meat and poultry products should be retained. If the Agency does replace the current regulations with the proposed performance standards, it plans to issue a revised version of the current regulations as compliance guides for industry.

In summary, the proposed rule:

- Defines a performance standard for food safety
- Defines a standard on adulteration
- Retains training requirement
- Encourages flexibility and innovation
- Removes prescriptive requirements
- Remove overlap with HACCP requirements