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Establishment of an FDA-approved international Better Process Control School for food canning supervisors

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TITOLO

Istituzione di una Better Process Control School approvata dalla FDA a livello internazionale per i supervisori di alimenti conservati in scatola

KEY WORDS

Better Process Control School (BPCS), Food and Drug Administration (FDA), *Clostridium botulinum*, Code of Federal Regulations (CFR) food canning

PAROLE CHIAVE

Better Process Control School (BPCS), Agenzia per gli alimenti e i medicinali (FDA), *Clostridium botulinum*, Codice di Regolazione Federale (CFR) alimenti in scatola

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Summary

Foreign manufacturers of acidified and low-acid canned foods who export to the United States must comply with provisions of Title 21, Code of Federal Regulations (CFR), Parts 108, 113, and 114. The regulations require that all operators of retorts, thermal processing systems, aseptic processing and packaging systems and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction appropriate to the preservation technology involved and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. The purpose of the Better Process Control School (BPCS) is to help food canneries to meet the safety requirements set by the United States CFR, which are to ensure safety from harmful bacteria and their toxins, especially *Clostridium botulinum*. The United States Food and Drug Administration (FDA) approve these schools, and those who successfully pass the course are registered with the FDA. A number of foreign entities have sought assistance from FDA to present a BPCS often as a means to upgrade their countries acidified and low-acid canned food industry or to become more informed about the United States' regulatory requirements for these industries in order to facilitate importing into the United States of America. Because of the obvious benefits, the FDA has not discouraged these efforts. However, past experience has demonstrated the necessity for FDA's Center for Food Safety and Applied Nutrition (CFSAN) to participate from the beginning in directing efforts to establish a "school", reviewing specific plans for its conduct, as well as participating in and monitoring any "school". Obviously, for a successful program of this type, maintenance and uniformity of "school" conduct, content and performance standards are important considerations in the FDA/CFSAN decision regarding approval. In this presentation we will discuss some basic components of the BPCS and procedures to work with the CFSAN to present a regular school that can be considered an official "BPCS" authorized by the FDA and which may be approved by the Commissioner of FDA and may be presented a number of times in the future by a foreign institution.

Riassunto

I produttori esteri di alimenti conservati in scatola, acidificati e a bassa acidità, che esportano verso gli Stati Uniti devono conformarsi alle disposizioni del Titolo 21 del Codice di Regolazione Federale (CFR), parti 108, 113 e 114. Le normative prevedono che tutti gli utilizzatori di storte, di sistemi di trattamento termico e di sistemi di lavorazione e di confezionamento asettico e gli ispettori di chiusura dei contenitori devono essere sottoposti alla supervisione operativa di una persona che ha frequentato e completato con successo l'istruzione prescritta dalla scuola approvata dall'FDA. Lo scopo della Better Process Control School (BPCS) è quello di aiutare le industrie conserviere alimentari a soddisfare i requisiti di sicurezza fissati dal CFR degli Stati Uniti, che devono garantire la sicurezza da batteri nocivi e dalle loro tossine, in particolar modo il *Clostridium botulinum*. L'Agenzia per gli alimenti e i medicinali americana (FDA) approva queste scuole, e coloro che superano il corso sono registrati presso la FDA. Un certo numero di soggetti stranieri ha cercato assistenza da parte della FDA per presentare una BPCS spesso come mezzo per aggiornare i propri paesi sulle procedure relativamente ai cibi acidificati e a bassa acidità dell'industria conserviera alimentare o per essere più informati sui requisiti in materia regolatoria degli Stati Uniti per facilitare l'importazione in questo paese. A causa dei benefici evidenti, la FDA non ha scoraggiato questi sforzi. Tuttavia, l'esperienza passata ha dimostrato la necessità per la FDA di un Centro per la Sicurezza Alimentare e la Nutrizione Applicata (CFSAN) per partecipare fin dall'inizio nel dirigere gli sforzi per creare una "scuola", rivedendo i piani specifici per la sua condotta, così come nel partecipare e monitorare qualsiasi "scuola". Ovviamente, per il successo di un programma di questo tipo, il mantenimento e l'uniformità della condotta della "scuola", lo standard di contenuti e di prestazioni sono considerazioni importanti nell'approvazione di decisioni riguardanti la FDA/CFSAN. In questo lavoro si discuterà di alcune componenti fondamentali della BPCS e delle procedure per lavorare con il CFSAN per presentare una scuola regolare, che possa essere considerata una "BPCS" ufficiale autorizzata dalla FDA, approvata dal Commissario della FDA.

Introduction

The US Congress, through the Food, Drug and Cosmetic Act, gave FDA the authority to regulate the food industry to ensure that foods are safe and sanitary. Congress gave FDA jurisdiction over all foods except for those with 3% meat or more, or foods with 2% poultry or more. Those are under the jurisdiction of the US Department of Agriculture, Food Safety Inspection Service. FDA, however, has jurisdiction over exotic and game meats and poultry. FDA also regulates alcoholic beverages, except wine beverages with less than 7% alcohol. FDA creates regulations to this end through public comments. FDA issues guidance documents to help understand the agency's thinking behind the regulations and interpretation of the law.

There are two basic requirements for all FDA-regulated foods, including acidified and low-acid canned foods:

- Labeling regulations as indicated in 21 CFR Part 101. It helps ensure fairness and proper nutrition. Label information must be conspicuously displayed and in terms that the ordinary consumer is likely to read and understand under ordinary conditions of purchase and use. The labeling regulations help prevent misbranding.

- The good manufacturing practice (GMP) regulations, which are codified as 21 CFR Part 110, explain what is needed to maintain sanitary conditions in food establishments. These tell what kinds of buildings, facilities, equipment, and maintenance are needed, and the errors to avoid, ensuring sanitation. They also deal with such matters as building design and construction, lighting, ventilation, toilet and washing facilities, cleaning of equipment, materials handling, and vermin control. GMP's help prevent adulteration.

Prior to 1973, there were no additional regulations for LACF or acidified foods. These foods only had to comply with the general provisions of the FD&C Act and the GMP regulations. FD&C Act Section 402(a)(4) states that a food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health. In the past, only 21 CFR Part 110 covered all foods in terms of GMP's for the manufacturing, packing and holding of foods. These regulations still apply to all foods including LACF and acidified. Current GMP indicated in 21 CFR Part 110 for manufacturing, packing, or holding human food ap-

plies to all foods. However, the laws and regulations at the time proved insufficient to protect the consumer when it comes to canned food.

Need for a Better Process Control School

Hazards in foods can be chemical, biological and physical. Biological hazards are caused by a few pathogenic bacteria. The most troublesome bacteria in foods are *Staphylococcus aureus*, *Listeria monocytogenes*, *Clostridium perfringens*, *Clostridium botulinum*, *Salmonella enteritidis*, and *Shigella* sp. Thermal under-processing and post-contamination of low-acid and acidified canned foods (LACF and AF) can spoil these foods as they can allow growth of *C. botulinum* spores. *C. botulinum* produces a very potent neurotoxin. It is estimated that a cup-full of these neurotoxin could wipe-out the entire world human population. Botulism is a serious illness that paralyzes the nerves so that the muscles cannot contract. The respiratory failure and paralysis that occur with severe botulism may require a patient to be on a breathing machine (ventilator) for weeks and may require intensive medical and nursing care, in some cases ending on death of patients. The classic symptoms of botulism

include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness. Constipation may occur. The doctor's examination may reveal that the gag reflex and the deep tendon reflexes like the knee-jerk reflex are decreased or absent. These are all symptoms of the muscle paralysis that is caused by the botulinum neurotoxin. If untreated, these symptoms may progress to cause paralysis in various parts of the body, often seen as a descending paralysis of the arms, legs, trunk, and breathing muscles. In food-borne botulism, symptoms generally begin 18-36 hours after eating a contaminated food, but they can occur as early as six hours or as late as 10 days afterward.

Botulism due to under-processing caused serious outbreaks in the 70's (1965, spinach; 1971, Vichyssoise and chicken vegetable soup; 1973-74, mushrooms; 1974, beef stew; 1980-81, mushrooms; 1982, peeled tomatoes). Botulism due to defective cans caused serious post-contamination outbreaks (1941, mushroom sauce, 3 cases, 1 death; 1963, tuna, 3 cases, 2 deaths; 1974, tuna; 1978, salmon, 4 cases, 2 deaths; 1982, salmon, 2 cases, 1 death). In 1973 21 CFR Part 113 contained only one paragraph for heat-treated acidified foods. That same year, it was recorded 7 cases of botulism in pickled green pep-

pers, one case in marinated mushrooms and 29 foreign firms imported pimentos and hearts of palm that were not acidified properly.

As consequence of these deathly outbreaks consumers became suspicious of canned foods in general and demanded more stringent and appropriate food regulations. FDA and USDA tackled this problem by focusing on critical control points during processing of LACF and AF applying the Hazard Analysis Critical Control Point (HACCP) seven principles devised by NASA in the 60's to provide safe foods for the space program. The regulations devised by FDA to protect consumers from botulinum outbreaks due to under-processing of LACF and AF are indicated in 21 CFR Part 113 and 114, respectively.

21 CFR Part 113 started off defining low-acid canned foods as any food with pH (acidity) greater than 4.6, aw (water activity) greater than 0.85 and not refrigerated or frozen. It addresses hermetic containers and suitability. After all, canned foods are processed at high heat and pressure and exposed to high moisture. It must allow proper heat transfer to the product. The container must not add any harmful contaminants to the food product, for example, metal oxide or rust. The container plays an important

role in the product shelf-life as well. This part of the regulation also requires the advice of a Process Authority. These are qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The regulation defines the commercial sterility requirement, retort design, controls and instrumentation. It mandates the creation and maintenance of process records. It addresses process deviations and corrective actions. It explains critical elements, including the container closure. Last, but not least, it mandates training of key personnel (canning supervisors and retort operators).

21 CFR Part 114 started off defining acidified foods and acid foods (natural pH greater than 4.6; final pH under 4.6; aw greater than 0.85; not refrigerated or frozen; not fermented), exceptions and exclusions. It lists acidification procedures. It requires that the scheduled processes are designed by a qualified person with expert knowledge and experience in acidification and processing of acidified foods. It addresses process deviations and how to handle them. It describes methods that may be used to determine pH or acidity. It mandates the creation and maintenance of records to document

the processes. Again, last, but not least, it mandates training of key personnel.

Setting up a Foreign Better Process Control School

Training of key personal of canning operations is done through the Better Process Control School (BPCS) administered by FDA and offered by several US Universities since 1978. This course usually lasts four days, during which students need to demonstrate understanding of critical control points during processing of LACF and AF. Usually 17 chapters are covered during this training. The official textbook "Canned Foods: Principles of Thermal Process Control, Acidification and Container Closure Evaluation", slides and tests for each chapter have been devised in English and translated to Spanish. BPCS is offered in English and Spanish several times per year in different Univer-

sities in the US. The regulations and training program have been very successful to reduce the botulism outbreaks in commercial canned products in America.

Training of canning supervisors is demanded even for foreign companies that export LACF and AF to the US.

The procedure to set up a foreign FDA-recognized BPCS involves sending a request letter to FDA through a sponsoring institution (American University with established BPCS program). A Foreign counterpart institution needs to be indicated.

Planning a foreign BPCS with FDA recognition requires:

- Letter from the foreign counterpart University
- Curriculum Vitae of Instructors
- Topics and Schedule
- Student Evaluation Forms
- Proposed Certificate of Attendance
- Proposed Certificate of Satisfactory Completion
- Draft of Promotional Advertising

Letter of Invitation from American BPCS Coordinators to FDA CFSSAN officer

FDA is willing to support foreign BPCS that will help ensure safe LACF and AF imported to the US from foreign countries by proper training of canning supervisors and other key personnel. In the future it is expected that the training material for this course can also be translated to other languages. A close interaction between academic and technical translators will be important to prepare teaching materials that can be suitable for training key canning personnel with various academic and technical backgrounds.

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