

## Biography

# William R. Cole

**Director HACCP Programs & Regulatory Affairs  
TechniCAL, Inc.  
Washington D.C. Area Office**

**Director, HACCP Programs and Regulatory Affairs,  
TechniCAL, Inc.**

## Career Summary

Bill Cole spent 25 years with the U.S. Food and Drug Administration, beginning his career as a Field Investigator in the Denver District Office in 1971. He transferred to the Boston District Office in 1978 to take the position of Food Specialist; then to the Baltimore District Office in 1981. In 1982, Bill was promoted to the position of National Expert/Food Processing with FDA's International and Technical Operations Branch in the Office of Regulatory Affairs, and in 1994 transferred to the Center for Food Safety & Applied Nutrition (CFSAN) as Special Operations Officer in the Division of HACCP Programs. Bill retired from FDA in January, 1997 and began full time employment with TechniCAL, Inc. as Director of HACCP Programs and Regulatory affairs.

## FDA Experience

### INVESTIGATOR

Bill was one of the FDA's first Field Investigators to be trained (1973) in using the Hazard Analysis and Critical Control Point (HACCP) approach as a systems evaluation tool. He has inspected a wide variety of food processing operations-both foreign and domestic- including low-acid canned foods (LACF); acidified foods; frozen heat-and-serve type foods; cacao products and confectionery, fresh and dehydrated pasta products; specialty sauces; infant formula; and medical foods. He has developed a highly-specialized expertise in evaluation of processing and packaging equipment and operational procedures for compliance with applicable FDA guidelines and regulations, particularly in the area of LACF, including aseptic.

Such evaluations have included review of LACF process filing forms and reconciling the information on these forms with process source documentation, as well as conformity of the operations on the plant floor to the design of the process.



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### **LACF**

His experience in the area of LACF processing include research projects dealing with temperature distribution studies in steam still retorts, as well as heat penetration into a number of different LACF products packed into metal cans. In addition, he has studied the causes of seam defects in low-profile, rectangular metal cans. He has also written sections in FDA's Investigations Operations Manual on LACF inspectional techniques (including the section on evaluation of aseptic processing and packaging) and on conducting non-LACF HACCP inspections.

### **HACCP**

While at CFSAN, Bill was Chairman of the Pilot Coordination Working Group, a task force responsible for implementing and monitoring FDA's Voluntary HACCP Pilot Program with the food industry. In this capacity, he was responsible for the formatting of procedures to be used in conducting the Pilot Site Evaluations; and for training FDA Field Investigators and state inspectors who were to be part of the Site Evaluation Teams. In this latter capacity, he developed the course format and was the course coordinator and principal instructor in three (3) FDA HACCP Pilot Training Courses. He participated in the review of numerous HACCP programs, some instituted or proposed as a result of regulatory action, both for domestic and imported products. He also participated in the development of the Seafood HACCP rule and was a principal contributor to the GMP portion of the proposed infant formula rule.

### **TRAINING**

Because of his inspectional expertise and knowledge of regulatory requirements involving a wide variety of food processing and packaging systems, Bill has presented over 100 training seminars and workshops, involving various aspects of evaluating food production operations using HACCP-based techniques. These training courses have been presented to a wide variety of local, state, Federal and foreign government personnel, as well as academia and industry, both nationally and internationally. In addition, Bill was one of a select cadre of instructors who developed a two-week HACCP training-the-trainer program at the request of the Food and Agricultural Organization of the United Nations.

### **FDA History**

- Field Investigator- FDA Denver District- 1971



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- Food Specialist- FDA Boston District- 1978  
FDA Baltimore District- 1981
- National Expert/Food Processing,  
FDA's International & Technical Operations Branch- 1982
- Special Operations Officer, FDA/CFSAN/Division of HACCP Programs- 1994
- Retired- January, 1997

## FDA Career Highlights

- Chairman of Voluntary HACCP Pilot Program Coordination Working Group
- Primary drafter of GMP portion of proposed Infant Formula Rule
- Chaired ad hoc committee to determine better monitoring of foreign LACF processors
- Lead & primary instructor in developing 3 national training courses for field investigators & state inspectors participating in Voluntary HACCP Pilot Program
- Lead FDA Investigator on foreign inspection trips to Thailand, England, Holland, China, Malaysia, and Spain.
- Worked with an FAO sponsored team in Rome to develop 2 week training course in HACCP
- Development and presentation of model regional LACF training program for FDA investigators and state inspectors.
- One of select cadre of three that established 9-course LACF training curriculum at request of government of Thailand.

## Techni**CAL**, Inc. Experience

Bill began employment with Techni**CAL** after his retirement from FDA in January, 1997. He is the principal company contact at Techni**CAL** for all HACCP related work, regulatory compliance inspections/audits, and all FDA and/or USDA regulatory compliance issues. Bill is also the lead instructor for all of Techni**CAL**'s HACCP training courses/workshops and has conducted courses for Techni**CAL** in the U.S., Thailand, and the Philippines, while also participating as an instructor in Techni**CAL**'s Basic Thermal Processing course.

## Techni**CAL** Highlights

- Development of Techni**CAL**'s "HACCP Services Division"
- Development of Techni**CAL**'s "HACCP Training Curriculum"
- Development of Techni**CAL**'s "LACF SOP Document" and "LACF Inspection Form"
- Authored technical papers on "Histamine Formation in Canned Tuna... CCP or CP", and "HACCP Verification Procedures"



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- Lead Instructor in 5-day HACCP Certification Course for Seafood industry in Bangkok, Thailand
- Developed and conducted FDA Policy Seminars for Seafood industry in Thailand and Philippines
- Team Leader for evaluating and organizing HACCP programs & regulatory compliance programs for the Tuna Industry in Philippines
- Lead investigator for approval of Aseptic process in Belgium
- Establishing format for process source documentation for product and package in an aseptic processing and packaging system.
- Development with USFDA/National Center for Food Safety & Technology engineer, a procedure for calculating expanded flow through the hold tube due to water addition and thermal expansion in direct aseptic product heating systems.
- Completion of Form FD-2541c's - Food Process Filing form Low-Acid Aseptic System - for aseptic processors in Korea.
- FDA policy "watchdog" for TechniCAL in the Washington DC area
- Writing LACF proposed regulation, with preamble, for the Korea Food & Drug Administration
- Expert Witness in court cases for three food safety related cases. In two cases testified in court, with his side winning both cases. In the third case, submitted an expert witness statement which was sufficient and instrumental, according to counsel, in winning a case brought by a foreign food processor against the Bureau of Customs and Border Protection and the international Trade Commission.

## Professional Memberships

- Professional Member of the Institute of Food Technologists (IFT)
- Member of the Institute of Thermal Processing Specialists (IFTPS). As one of three individuals on the Temperature Distribution Sub-Committee for Steam Still Retorts/Committee on Temperature Distribution, established the very first protocol published by the Institute, for conducting temperature distribution studies in steam still retorts. He also was the lead in developing the final protocol for the conduct of temperature distribution in water spray and water cascade retorts.

