CHAPTER 1: General Information

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

THE GUIDANCE

This is the fourth edition of the Food and Drug Administration's (FDA's) "Fish and Fishery Products Hazards and Controls Guidance." This guidance relates to FDA's Fish and Fishery Products regulation (called the Seafood HACCP Regulation, 21 CFR 123, in this guidance document) and the Control of Communicable Diseases regulation, 21 CFR 1240, that require processors of fish and fishery products to develop and implement HACCP systems for their operations. Those final regulations were published in the *Federal Register* on December 18, 1995, and became effective on December 18, 1997. The codified portion of the regulations is included in Appendix 8.

This guidance is being issued as a companion document to "HACCP: Hazard Analysis Critical Control Point Training Curriculum," which was developed by the Seafood HACCP Alliance for Training and Education. The Alliance is an organization of federal and state regulators, including FDA, academia, and the seafood industry. FDA recommends that processors of fish and fishery products use the two documents together in the development of a HACCP system.

This guidance document will be maintained on the FDA.GOV website, which should be consulted for subsequent updates. Copies of the training document may be purchased from:

Florida Sea Grant

IFAS - Extension Bookstore University of Florida P.O. Box 110011 Gainesville, FL 32611-0011 (800) 226-1764

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