

## **FDA GUIDANCE LEVELS**

All human foods that are introduced or delivered for introduction into interstate commerce in the United States or its Territories, must comply with the Federal Food, Drug and Cosmetic Act (FD&C Act). If the foods are offered for sale as consumer commodities, they must also comply with the requirements of the Fair Packaging and Labelling Act (FPLA). Regulations promulgated under these Acts can be found in Title 21 of the *Code of Federal Regulations (CFR)* mentioned in the previous paragraph.

It is difficult to identify a single reference which contains a compilation of standards and guidelines which can be used to determine if a seafood products meets United States regulations. This is because unique conditions, such as, processing procedures, investigational evidence and the final use of the product, may affect the evaluation of the case. As a result, Food and Drug Administration legal actions are considered on a case by case basis. The Compliance Policy Guides, Compliance Programs, and Import Alerts may be obtained by contacting:

Mary Hodge  
Food & Drug Administration  
Freedom of Information Office (HFI-35)  
5600 Fishers Lane  
Rockville, Maryland 20857

## **NEW REGULATIONS**

United States Department of Health and Human Services Secretary Donna E. Shalala announced on January 21, 1994, a major new food safety initiative in which the Food and Drug Administration will require the U.S. seafood industry to establish safety controls subject to regulatory oversight and review. These regulations will also have a major impact on Canadian fish and seafood exporters examining the United States market. The seafood safety regulations are based on the Hazard Analysis Critical Control Point (HACCP) concept.

HACCP is a system designed to prevent safety hazards from occurring that can be applied by food processors and importers to ensure that their products are as safe as possible for human consumption. Because nearly 60 percent of seafood available to U.S. consumers is imported, the FDA is proposing to require that all imported seafood be processed under HACCP systems.

The new regulations will cover all U.S. seafood processors, packers, warehouses and importers and will include all fresh, frozen and low-acid canned foods produced totally or partially from all aquatic animals except birds and mammals. Transportation companies that carry, but do not otherwise process, fish and fishery products are not included under the regulations.

Seafood retailing is not included, but an updated food code was released by the FDA in conjunction with the announcement of the new regulations which will serve as guidelines to U.S. food retailers and restaurants in the handling, cooking, storage and display of seafood products. Current regulations on fresh and frozen mollusc and shellfish are being amended. Fishing vessels are not included, but at-sea processing vessels are included in the new FDA regulations.