

6. Testing and Retraining

96. Several comments supported the mandatory use of testing to assess whether an individual has successfully completed HACCP training. Two comments further recommended that the agency could consider the training requirement to be met if a person successfully passes an examination.

The agency is not opposed to testing at the end of a course but prefers not to mandate that courses include tests. Trainers will be free to include or not include testing as part of their training efforts. The issue of student evaluation is one that is still being debated in the Alliance relative to Alliance-sponsored training courses.

However, testing alone does not provide the kind of exposure to the concepts of HACCP that is necessary to result in company understanding and commitment. The function of training is to prepare industry to meet the requirements of the regulations, not to test competency. The true test will be whether processors are able to implement their HACCP systems. Processors will be judged as plans are reviewed, and plant operations are evaluated, during inspections.

97. A few comments recommended mandatory retraining or continuing education. The comments stated that as new information about the science of fish and fishery products hazards and the technology of their control becomes available, there will need to be some method for introducing this information to previously trained individuals. One comment, on the other hand, urged that training be limited to a single event and not be subject to periodic renewal.

The primary purpose of the training is to teach the fundamentals of HACCP. These are unlikely to change over time. A comprehensive discussion of seafood hazards and controls is far too extensive for inclusion in a 3-day training session. The agency has concluded that information about the technology that is available to control hazards should be made available to the industry through the Guide, the Alliance Compendium of Established Processes, and other modes of technical assistance. FDA supports the idea of continuing education and will encourage it, but the agency is not prepared to mandate it in these final regulations.

98. A comment suggested that the regulations mandate remedial or enhanced training for a first time violator whose infractions have resulted from a misunderstanding of HACCP principles.

Whenever an infraction occurs, the nature of the remedy that is warranted

depends on factors such as the public health significance of the infraction. The agency has administrative warnings and, when necessary, a range of regulatory actions available to it. (See the "Compliance" section of this preamble for a more thorough discussion of compliance philosophy under HACCP and available remedies.) Ultimately, however, it will be the processor who will be responsible for correcting the deficiencies in its HACCP system. Part of that responsibility will be determining the most appropriate method of resolving any failure to fully understand HACCP principles, whether through remedial training, hiring a consultant, or taking some other step. So long as an appropriate outcome can be obtained, FDA would prefer not to mandate any particular method of remediation in these regulations. Processors certainly may wish to consider additional education as an option, however.

7. Gradations of Training

99. Several comments addressed whether the HACCP training requirement could be satisfied by different gradations of training, depending on the complexity or size of the operation or on the degree of risks posed by the product being produced. The majority of these comments supported the concept of variable levels of HACCP training. Most did not provide the basis of their support. Those that did suggested that small or large scale processing of low-risk products would not likely require any special training, and that small scale processing of even high-risk products would allow for individual examination of every fish, an option that is not possible in large scale processing. One comment further suggested the use of variances to exclude certain industry members from the training requirement, rather than providing a blanket exemption for a segment of the industry.

A minority of the comments on this subject opposed any variations in the level of training. Several of these comments stated that the necessity for HACCP education and training does not vary based on the size of a company, and that a standard training curriculum should be developed for all companies, regardless of their size. Some of these comments stated that smaller processing operations may be inherently less safe, and that, cumulatively, they represent a large amount of the seafood making its way to the consumer. One comment stated that smaller processing operations may actually have a greater need for employee training, compared to

some larger processing operations that may already have trained staff.

The agency agrees with the comments that suggested that the need for HACCP training does not vary solely by the size of the processor. An understanding of the principles of HACCP is essential for the successful implementation of a HACCP program, regardless of establishment size. The agency agrees with the assertion that, in many cases, the training needs of small businesses may, in fact, be greater than those of large firms, because they frequently lack the trained quality control and research and development staffs that are common in large firms. Moreover, small businesses comprise a significant portion of certain high-risk segments of the fish and fishery products industry, such as processors of molluscan shellfish and cooked, ready-to-eat products. Training will be critical to ensure the success of HACCP in these segments.

Although the agency expects that the complexity of HACCP plans will vary with the number and type of hazards associated with a processing operation, an understanding of the basic principles of HACCP, and how to apply those principles to the processor's operations, will remain essential. The curriculum under development by the Alliance is designed to provide a very basic grounding in these matters. As stated earlier, the Alliance has acknowledged a need to tailor part of the course so that it can be directed toward specific industry segments. This approach may be the best way to provide flexibility in the program, so that training can match the degree of complexity and risk that is encountered by the processor. FDA will continue to encourage the development of industry-specific training features.

The agency is not persuaded that the ability of a processor to individually examine all fish because of the small scale of operations will reduce the processor's need to understand the hazards associated with seafood and the specifics of a systematic approach for controlling them. FDA has long taken the position that observing each fish on an assembly line is an inappropriate way to ensure seafood safety (Ref. 208, p. 4146). While matters relating to the quality of the fish can be observed in this manner, safety matters often cannot.

8. Duties of the Trained Individual

100. Several comments suggested that a firm be permitted to hire a consultant, or an outside expert, who is not an employee of the firm, to perform the functions required of a trained individual. Two trade associations