

trained individual at each processing facility. Those that provided reasons for their support contended that properly trained personnel are essential to the development and effectiveness of HACCP controls, and that training is necessary to ensure consistency of approach.

Those few comments that expressed reservations about the overall HACCP training requirement generally acknowledged the need for a trained individual in the plant but opposed a compulsory training program. Two comments, from State governments, expressed concerns about the financial burden of training on small businesses and questioned the need for making such a provision mandatory.

The overwhelming support in the comments for HACCP training is indicative of the nearly universal view that training is essential to the effective implementation of a HACCP system. As stated in the preamble to the proposed regulations, this view is shared by the NAS based on the success of the training requirement in FDA's HACCP-based regulations for low-acid canned foods at part 113 (Ref. 54). The primary concern expressed about mandatory training is the cost.

The agency is convinced that its efforts with the Alliance will facilitate the development and implementation of a low cost training program. As mentioned above, the Alliance is a cooperative effort between Federal and State food regulatory agencies, academia, and the fish and fishery products industry to provide support to the industry in meeting its needs relative to HACCP training, technical assistance, and research. Presently, the Alliance Steering Committee is comprised of representatives of FDA, the U.S. Department of Agriculture (USDA), NMFS, AFDO and its six regional affiliates, the Sea Grant Colleges, the ISSC, the National Fisheries Institute, and the National Food Processors Association (NFPA).

The goals of the Alliance are to develop: a HACCP training course that will meet the requirements of these regulations, a mechanism for delivering the training to the fish and fishery products industry, a compendium of established methods for controlling hazards in the fish and fishery products industry, and a mechanism for coordinating the research efforts of the participating agencies to facilitate the development of improved methods of hazard identification and control.

The training course materials are in an advanced stage of development and are expected to be publicly available shortly after the publication of these

regulations. The AFDO regional affiliates have agreed to work within their regions to identify regulatory and industry training needs and qualified trainers who are interested in participating in the Alliance-sponsored training. They have also agreed to serve as the course coordinators for the Alliance-sponsored training, which will be conducted on a cost-recovery basis.

The Alliance is developing a 3-day course, divided about equally among: (1) The fundamentals of HACCP, based on the recommendations of the NACMCF; (2) the requirements of these regulations and the recommendations of the Guide; and (3) a practical exercise in HACCP plan development.

FDA is sensitive to the concerns expressed about the cost of training but is optimistic that training will not be unnecessarily burdensome on small business, either in actual out-of-pocket expenses or in lost productivity. As was previously mentioned, FDA is working with the Alliance to produce a low cost, 3-day HACCP-training course for the seafood industry, that is intended to meet the requirements of these regulations. Current plans are for the course to be offered through a variety of public institutions, including Sea Grant colleges. As indicated earlier, in this setting the course is expected to be offered on a cost recovery basis. It is likely that the course will also be offered by private institutions, using their own fee structure.

The other cost associated with the training requirement is the lost productivity for the duration of the course. FDA is convinced that, with the flexibility in course structure, described elsewhere in this section, training can be taken at times when it would least affect the operations of the firm (e.g., during an off-season, at night). Moreover, FDA is convinced by the comments that, as a general rule, the benefits of training will significantly outweigh the burden. The agency has concluded that with certain modifications from the proposal as described below, training should remain a feature of these regulations.

The agency has made one modification in response to requests that it modify the training requirement to reduce financial burden, especially on smaller processors. FDA acknowledges that a short course in HACCP has its limitations. For example, a 3-day course might not have anything important to offer to an individual who has significant job experience working with or for an individual who is well-versed in HACCP. In such a situation, if the processor loses the trained individual, it should be able to replace

him or her with the individual who has, in effect, apprenticed with the trained individual without having to send the apprentice to a course in HACCP training, assuming, of course, that the apprenticeship has imparted a level of knowledge at least equivalent to that that could be provided by the training. The agency has modified the regulations to provide for this kind of situation by permitting adequate job experience to qualify an individual to perform the functions of the trained individual.

Note that all references in this preamble to a trained individual mean an individual who meets the requirements of § 123.10 through either completion of a course or job experience that provides an equivalent level of knowledge.

2. Who Should Provide Training?

90. A significant number of comments identified organizations or individuals that they considered to be qualified to conduct or develop HACCP-training courses. The majority of the comments, which included remarks from processors, trade associations, and State governments, suggested that FDA should either conduct such training or at least approve the relevant course material. A few of the comments that recommended that FDA conduct the courses also recommended that FDA provide the courses at no cost or financially support the training. The comments that endorsed FDA approved courses asserted that this approach would result in a standardized, comprehensive training program that emphasizes the minimum acceptable HACCP requirements.

Other comments recommended that training programs could be conducted by NFPA or other trade associations, ISSC, Sea Grant colleges and other academic institutions, consultants, and State and local regulatory agencies. The comments acknowledged the cost savings that could be realized with trade association-provided training and through the HACCP training experience already possessed by the NFPA. One comment suggested that allowing many training programs would offer hundreds of professionals the opportunity to contribute to the development of HACCP. A few comments suggested that FDA publish a listing of approved training courses.

A comment from the ISSC cautioned that organization does not support the shifting of public health training in the area of molluscan shellfish away from itself. The comment further stated that the organization would work cooperatively with the Alliance in the development of a HACCP-training