

course, which it suggested should be Federally subsidized and ISSC endorsed.

A few comments suggested that the Alliance be permitted to develop the standard for HACCP training, and that the results be shared with all prospective trainers. A few additional comments urged that HACCP training be based on the recommendations of NACMCF, because such efforts would result in a training program that was well defined.

FDA generally agrees with these comments. The agency does not intend to run HACCP-training courses for the industry. Rather, FDA must, of necessity, focus its HACCP training on government investigators. The agency anticipates that industry training will be conducted privately and through academia. This division of labor is based on the model that has worked well for the training requirement for low-acid canned foods.

FDA agrees, moreover, that there should be widespread opportunity for conducting HACCP training. It is not the agency's intent to specify or limit the field of qualified trainers.

The training course that is under development by the Alliance is based on the recommendations of the NACMCF. After reviewing the final draft of the Alliance training materials, FDA intends to publish a notice of availability of the documents in the Federal Register. It is the agency's intent to utilize the Alliance materials as the standard against which other course materials may be judged.

The agency strongly encourages trainers to evaluate their courses, past, present, and future, against the Alliance materials when they become available and to modify or adapt curricula, where necessary, to ensure that they are consistent with, and provide at least an equivalent level of instruction to, the Alliance course. Where previously conducted training fails to meet this standard, it may suffice to provide supplemental materials or instruction so that the cumulative training is at least equivalent to the Alliance course. FDA also encourages the fish and fishery products industry to confirm with past or prospective trainers that a particular course is equivalent to and consistent with the Alliance materials. The agency has no plans to publish a list of "approved" courses other than the Alliance course materials.

Finally, it should be noted that FDA resources will not be sufficient to fund the training of all appropriate regulators (i.e., State or local regulators). The agency is confident, however, that Alliance training will provide a low cost

opportunity for high quality HACCP training for State or local regulators as well as for processors.

Because FDA will not be approving in advance specific courses other than the Alliance curriculum, and in response to comments, the final regulations have been modified at § 123.10 to require that training courses be "at least equivalent to the standardized curriculum recognized as adequate by the U.S. Food and Drug Administration." FDA had proposed to require that training courses be "approved by the Food and Drug Administration."

3. Should Training Be "Grandfathered?"

91. A large number of comments addressed the question of whether training in HACCP received before the effective date of these regulations should be "grandfathered" as fulfilling the training requirement. All of these comments supported the grandfathering of such training. Many of the these comments recommended specific training courses that FDA should grandfather. Approximately half of these comments requested that those trained under NMFS' HACCP training program be grandfathered. Those that provided reasons referenced the large number that had been trained at the time of the writing of the comment (1,310 domestically and 394 overseas) and stressed that NMFS' training was more comprehensive than that which would be necessary under FDA's HACCP approach, especially because the NMFS program covers nonsafety hazards in addition to safety hazards.

Other comments supported grandfathering HACCP courses conducted by NFPA, Sea Grant colleges, State regulatory agencies and those organizations sanctioned by such agencies to provide HACCP training, and Pacific Fisheries Services. One comment suggested that graduation from a Better Process Control School, as required by parts 113 and 114 for processors of acidified and low-acid canned foods, should be considered to meet the requirements of these regulations. Another comment urged that any training program based on the HACCP principles recommended by the NACMCF should be grandfathered.

One comment suggested that, in order to grandfather courses, FDA would need to develop a system to determine the effectiveness of the training that has been conducted. The comment recommended the use of testing or curriculum review as evaluation tools. The comment further encouraged the development of a formal approval process for previously conducted training.

FDA has concluded that it is not in a position to grandfather HACCP training received before the issuance of these regulations. Blanket grandfathering would pose the risk of sanctioning training that does not fully prepare processors for operating under these regulations, and case-by-case grandfathering would be unduly demanding on agency resources.

On the other hand, the agency will not presume that HACCP training received prior to the issuance of these regulations will have to be repeated. FDA will challenge the adequacy of prior training only when a processor's performance demonstrates a lack of understanding of HACCP principles.

Nonetheless, FDA encourages processors to update any prior training to ensure that they have a thorough understanding of the requirements of these regulations. It may well be that many traditional HACCP courses will need only minimal supplementation to accommodate them to the provisions of these regulations, and that there will be no need for a processor to repeat an entire course. As mentioned above, partial, supplemental courses may be offered, or reading materials developed by the course offerer and sent to the processor may suffice. There are numerous possibilities.

FDA is also not in a position to make determinations in advance about the acceptability of courses that will be offered after the issuance of these regulations. FDA agrees with the comment that, in order to do so, the agency would have to develop a system for course evaluation. Review of course materials, auditing of course presentations, testing, and other evaluation tools that FDA might have to employ are labor intensive and are not the most efficient use of agency resources. Rather, the adequacy of courses will have to be evaluated by FDA on a case-by-case basis, when inspectional or other evidence causes the agency to question whether the course meets the requirements of § 123.10.

The ultimate determination of the success of training is whether processors are operating effective HACCP systems. In the initial stages of the program, at least, FDA's primary focus will have to be on whether HACCP plans are adequate, and the systems are being effectively implemented. FDA's interest in the adequacy of training will increase when plans and systems fail to demonstrate an adequate understanding of HACCP and its application to seafood.

Nonetheless, FDA can state that the Better Processing School curriculum for