

acidified and low-acid canned foods will not be adequate to meet the training requirement of these regulations. The Better Processing School was developed to instruct acidified and low-acid canned food processors in how to safely process such products to control the hazard of the development of botulinal toxin in accordance with the requirements of parts 113 and 114. The course does not provide instruction in the principles of HACCP or address other hazards (e.g., histamine development) to which these products might also be exposed.

#### 4. Course Curriculum

92. A few comments suggested that the training be divided into a basic HACCP core and interchangeable segments based on the portions of the industry of interest to the students (e.g., vessels, cooked, ready-to-eat fishery products, molluscan shellfish, and smoked fish).

As mentioned previously, the Alliance course includes three segments: A basic HACCP core, the requirements of these regulations, and the development of a HACCP plan. The first two segments are applicable to the entire fish and fishery products industry. The Alliance has acknowledged the need to develop industry-specific features for the third segment. The agency is in agreement with the Alliance and with the comment in this regard and would encourage the development of such directed courses.

93. In response to FDA's invitation to comment on the advisability of alternate training formats, several comments expressed support for the use of video tapes by small processors of low-risk products. A few additional comments did not specifically address video taped training but stated that, while it is desirable to have uniform training, ultimately training should involve "whatever it takes." One comment suggested that home study courses and education via television might be acceptable alternatives to more formal, for-fee training mechanisms. A few comments opposed courses that consist exclusively of video tapes, based on concern for a potential limitation in the level of understanding that could result from this type of noninteractive training method.

FDA agrees with the comments that expressed concern with teaching methods, such as video tapes, that lack instructor/student interaction. However, in the interest of providing flexibility in meeting the training requirement of these regulations, the agency has concluded that any teaching format is acceptable so long as it provides a level

of understanding at least equivalent to that provided by the Alliance training program. FDA is aware that video tape training is widely used for a variety of purposes. The agency cannot conclude that video-based HACCP training will not accomplish the purposes of the training requirement. For remote site processors, video-based training may be the only practical method available.

It is unlikely, however, that two or three 2-hour video tapes, as one comment suggested, will provide an equivalent level of training to the 3-day Alliance course under development. On the other hand, a series of video presentations, perhaps in conjunction with a 1-day workshop, may be adequate.

94. A few comments addressed the length of the training course. One suggested that 3 days would be overly burdensome on small businesses because of the loss of manpower during the course. Another suggested that 3 days was not long enough to furnish the needed information. One comment suggested that the length of training should be based on the level of experience of the student and the level of complexity of the processing operation.

FDA has concluded, based, in part, on its participation in the Alliance, that the 3-day Alliance curriculum is the minimum necessary to develop an adequate understanding of HACCP principles and essentials of HACCP plan development. If the curriculum were reduced any further, processors would risk having to take more time later to implement their HACCP systems as a result of trial and error, and as a result, the quality of their HACCP programs would be jeopardized.

Nonetheless, FDA is not specifying in the regulations how long the course must take, only that it be equivalent in terms of curriculum to the standardized curriculum recognized as adequate by the agency. If true equivalency can be achieved in less time, FDA would have no objection. Moreover, depending upon the circumstances, FDA would have no objection to training that can be imparted in segments at convenient times so as to cause only a minimal disruption to the work schedule.

Section 123.10, therefore, states that the training must be "at least equivalent to the standardized curriculum recognized as adequate by the U.S. Food and Drug Administration." This provision will also accommodate the use of food processing experts, who have received training in HACCP that is far more extensive than that planned by the Alliance. FDA recognizes that it would be inappropriate to limit the

universe of experts to those who have taken a course based on the Alliance 3-day curriculum. The issue of the use of consultants and other experts will be further discussed later in this section.

#### 5. Do Importers Need Training?

95. A few comments suggested that FDA should provide separate or specialized training aids for importers. Two of these comments noted that importers have not, historically, been involved with the processing of seafood commodities. The comments requested that FDA work with trade associations that represent importers in setting up workshops, developing specialized training materials for importers, and recognizing training provided by foreign institutions.

FDA has reassessed the need for training to accomplish the HACCP functions assigned to importers, especially in light of changes in the imports provisions of these final regulations. These changes are fully discussed in the "Imports" section of this preamble. In summary, importers are now required to conduct verification activities but are no longer required to have full HACCP plans of their own unless they also meet the definition of a "processor." FDA has concluded that HACCP training, while desirable, is not essential to the preparation of importers' verification procedures, as specified at § 123.12(a)(2). For this reason, training is not required for importers, and all reference to required training for importer functions has been dropped from § 123.10.

Nonetheless, the agency is aware that importers may be unfamiliar with the technical aspects of fish and fishery product processing and HACCP control procedures. Knowledge about these matters would be helpful for purposes of verification. To meet this need, FDA plans to include in the Guide specific materials relating to importers' verification procedures. In addition, as has traditionally been the case, the agency intends to continue to interact with, and provide information to, the import industry through trade associations and other forums, within the limits of budget constraints. Moreover, importers may want to participate in the training courses that are offered by the Alliance.

Finally, the agency agrees with the comment that suggested that training overseas should be conducted by foreign institutions recognized for their expertise in seafood processing and HACCP control. This issue will be further discussed in the "Imports" section of this preamble.