that request. Additional comments addressed the specifics of the proposed generic-type requirements in § 123.7.

1. Should Corrective Actions Be Predetermined?

70. Approximately half of the comments supported the corrective action system proposed by the agency or a variation of it, and the other half called for mandatory predetermined corrective action plans. Many of those that supported mandatory corrective action plans urged consistency with the HACCP recommendations of the NACMCF. These comments noted that the NACMCF recommendations are consistent with Codex Alimentarius Commission standards. They predicted that compatibility of the final regulations with such international standards would minimize confusion for processors and importers, smooth international adoption of HACCP principles, and facilitate trade. The comments stressed that predetermining corrective action is an essential component of a processor's HACCP program, with the seven principles being so closely intertwined that overall success is probable only if all are intact.

A number of comments argued that a processor's implementation of a corrective action plan would eliminate indecision and confusion about what corrective action should be taken in the event of a deviation from a CL. For example, one comment pointed out that corrective actions written into the HACCP plan would eliminate the need for employees to substantiate to management the correctness of their response to a deviation, because the corrective action plan would provide the right actions to be taken for each particular deviation. A few comments stated that, if the appropriate corrective actions are detailed in the HACCP plan, responses by employees to CL failures are more likely to be immediate (reducing product losses) and effective (reducing wasted effort). These comments further noted that corrective action plans are particularly necessary when individuals qualified to make product safety evaluations are not readily available.

One comment asserted that the strength of the HACCP system is that it is preventive, and that corrective action plans are fundamental in preventing a product, for which there is a safety concern, from reaching the consumer. The comment further stated that written corrective action plans should provide for the documentation of the following: (1) The cause of the deviation, (2) the action taken to ensure that the deviation does not reoccur, (3) the results of the risk evaluation, and (4) product disposition.

Many comments did not agree that corrective action plans should be required. A few comments argued that developing a corrective action plan is impractical and can be unduly restrictive because of the diversity and complexity of seafood products and of seafood processing operations. One comment noted that many situations exist in which the appropriate response to a CL failure is not apparent until the details of the particular situation are known. Several stated that a corrective action plan is less preferable than having responsible and knowledgeable personnel, adequately trained in HACCP, available to evaluate a deviation from a CL. If such personnel are available, one comment noted, deviations can be handled on a case-by-case basis, with appropriate documentation of the disposition of the affected product.

Several comments argued that the lack of a corrective action plan is not sufficient evidence to demonstrate that a product is adulterated. The comments argued that the proposed requirement that a processor establish CL's and perform and record appropriate corrective actions when these limits are exceeded, provides sufficient demonstration of hazard control.

A number of comments that advocated the concept of predetermined corrective action plans urged that processors be given the option of writing such plans or of following a series of minimum mandatory actions, like those proposed by FDA, when CL failures occur. In the preamble to the proposed regulations the agency did, in fact, encourage processors to predetermine corrective actions as part of the preparation of a HACCP plan.

On this issue, the merits of the various approaches tend to balance. Consequently, FDA agrees with those comments that urged that the regulations provide processors with the option of developing their own corrective action plans as part of their HACCP plans or of following a generic model corrective action plan, provided in the regulations, should a deviation occur.

The agency accepts the view that predetermined plans have the potential to provide processors with benefits, as pointed out by the comments, such as faster action when a deviation occurs, less need to justify to management the appropriateness of the corrective action after it has been taken, and a more timely response to the deviation when trained or otherwise qualified individuals are not readily available to make determinations. On the other hand, FDA has not been provided with information on which it can conclude that these benefits—as desirable as they may be—need to be mandated in order to protect the public health. Processors can build them into their HACCP systems if they so choose, but the public health will be protected so long as shipment of the affected product into commerce does not occur until the significance of the deviation has been assessed and appropriately resolved.

This outcome is assured both with specific predetermined corrective action plans and with the minimum generic model that FDA is requiring as an alternative. Without additional evidence from actual experience, which was not provided by the comments, FDA cannot conclude that the overall success of HACCP depends on whether processors have specific predetermined plans for events that might not necessarily occur.

Consequently, FDA has revised § 123.7 to permit, but not to require, processors to include in their HACCP plans any written corrective action plans that they develop. When a deviation from a CL occurs, § 123.7(a) requires that processors either: (1) Follow a corrective action plan that is appropriate for the particular deviation, or (2) follow the series of actions provided in § 123.7(c). The steps in § 123.7(c) constitute a minimum generic model for corrective actions and, as will be explained below, closely match those that were contained in the proposed regulations.

The final regulations at § 123.7(b) define an appropriate corrective action plan as one that addresses both the safety of the product that was being processed when the CL failure occurred and the cause of the deviation. In this respect, the contents of the corrective action plan are consistent with the views of the NACMCF (Ref. 34, pp. 199–200). The corrective action must ensure that any unsafe product is not distributed.

FDA advises that action necessary to correct the product may involve any one or more of the following steps: Immediately reprocessing the product; diverting the product to another use where it can be used safely; segregating the product, holding it, and having it evaluated by a competent expert; or destroying the product. In order to ensure that subsequent product is not subjected to the same deviation, the corrective action must be sufficient to bring the process back under control (Ref. 34, pp. 199–200). FDA advises that such action may involve, where appropriate: adjustments to those process parameters that have an effect