would generate. FDA's experience with low-acid canned foods and acidified foods has demonstrated that review of these kinds of records is a critical verification tool. FDA is, therefore, adopting the proposed provision as § 123.8(a)(3) with one revision. As set out in the final rule, it requires that the HACCP-trained individual review the monitoring records of CCP's and the records that document the taking of corrective actions within 1 week of the making of the records, rather than before shipment, as a part of a processor's verification activities (§ 123.8(a)(3) (i) and (ii)).

FDA agrees, on the other hand, that this principle need not apply to the review of records of such verification activities as process control instrument calibration and product testing. The frequency of these activities will be variable and dependent upon the HACCP plan development process. Consequently, setting a specific review frequency for these records is not warranted. Section 123.8(a)(3)(iii) reflects this conclusion. It requires that the HACCP-trained individual review the calibration records within a reasonable time after the records are made, rather than before any additional products are shipped. It also applies the same ''reasonable time'' standard to any end-product testing records that are made.

The proposed regulations did not address the review of end-product testing records by a trained individual. The requirement in these final regulations for a review of such records reflects the principle contained in the proposal that there be a verification-type review by a trained individual of the HACCP records that are being created by the processor. In this respect, the responsibilities of the trained individual are unchanged from those that were contemplated in the proposal, although details relating to those responsibilities have been modified based on the comments.

Section § 123.8(b) requires that processors take appropriate corrective action whenever a review of a consumer complaint, or any other verification procedure, reveals the need to do so. This provision is essentially a restatement of the proposal regarding consumer complaints, expanded to include the results of verification procedures for purposes of emphasis. Verification was not specifically included in the proposal. FDA is including a reference to it here to remind processors not to preclude the possibility that information obtained through verification could lead to the taking of a corrective action. This possibility exists even though, more often than not, verification will not provide the kind of immediate feedback that the processor will receive from monitoring. Corrective actions based on information received through verification will be exceptions to the rule. However, processors should be mindful of the possibility.

7. Verifying the Hazard Analysis

Section 123.8(c) requires that, whenever a processor does not have a HACCP plan because a hazard analysis has not revealed any food safety hazards that are reasonably likely to occur and that can be controlled through HACCP, the processor must reassess the hazard analysis whenever a change occurs that could reasonably affect whether such a hazard exists. FDA has included examples of such changes in § 123.8(c). The list is identical to that provided in § 123.8(a)(1), for when a plan must be reassessed. Consequently, any change in these factors should warrant a reassessment to be certain that a plan is still not needed.

FDA has concluded that, under a mandatory HACCP system, the principle of verification applies equally to a decision that a HACCP plan is not necessary as it does to a decision that the plan continues to be adequate. Circumstances change, and processors must be alert to whether the exemption from the requirement to have a plan continues to apply to them.

Section 123.8(d) requires that processors document calibration and product testing in records that are subject to the recordkeeping requirements of the regulations at § 123.9. The requirement that records be kept of process monitoring instrument calibration was included in the proposed regulations at § 123.6(b)(5). The requirement that records of end-product testing be kept is consistent with the general recordkeeping principles of HACCP. The one exception is that FDA is not requiring records that document the review of consumer complaints. The agency is satisfied that the requirement for a processor to review consumer complaints relating to potential safety concerns will be sufficient for this kind of verification activity. Moreover, as explained in the discussion of consumer complaints elsewhere in this preamble, FDA is persuaded that most consumer complaints will involve matters unrelated to the mandatory HACCP system.

H. Consumer Complaints

1. Background

In the proposed regulations, FDA tentatively concluded that each processor's HACCP system had to utilize any consumer complaints that the processor receives that allege a problem with product safety. Several provisions described how consumer complaints were to be used. In one, FDA proposed to require that a processor's monitoring efforts include the use of consumer complaints, and that its HACCP plan reflect how they will be used. In a second provision, FDA proposed to require that, when a processor receives a consumer complaint that may be related to the performance of a CCP or that may reflect a CL deviation, the processor determine whether a corrective action is warranted, and, if so, take one in accordance with the specified corrective action procedures. FDA also proposed to require that the taking of such corrective actions be fully documented in records. Finally, FDA proposed to require that consumer complaints that relate to the operation of a CCP or to a possible CL deviation be included as part of the processor's HACCP records and be available for agency review and copying.

FDA's rationale for proposing these requirements was that consumer complaints may be the first alert that a processor has that problems are occurring that are not being detected or prevented by the processor's HACCP controls. While the goal of a HACCP system is to prevent all likely hazards from occurring, no system is foolproof. The agency tentatively concluded,therefore, that each HACCP system should take advantage of consumer complaints as they relate to the operation of CCP's. FDA also tentatively concluded that it might be necessary for the agency to review those complaints in order to be able to verify whether a processor is taking necessary steps to review its HACCP controls and take corrective actions as necessary in response to consumer complaints. The agency emphasized that it was referring solely to complaints relating to the operation of the HACCP CCP's (i.e., those that allege a problem with human food safety) and not to consumer complaints generally.

2. Consumer Complaints as Verification Tools

76. FDA received a large number of comments on the advisability of handling consumer complaints in the manner that the agency proposed. Generally speaking, the comments