A few comments suggested that such testing should be performed more frequently during plan development and validation, and then reduced to some lower level as part of a firm's verification efforts. Another comment suggested that testing should be performed quarterly by those processors with a poor record of compliance and annually by those with a good record.

Several comments suggested that the need for and frequency of product analysis should be established as part of the HACCP plan development process. One of these comments noted that the frequency of testing may fluctuate depending, in part, upon changes in personnel, raw materials, equipment, and product formulation.

A number of comments stated that end-product testing is a questionable method for measuring the success of a HACCP system. One of these comments stated that end-product testing measures the effectiveness of the plan for a small, finite portion of production and has limited value in measuring the success of the HACCP plan overall.

One comment stressed that finished product testing is contrary to the concept of HACCP, i.e., a reliance upon preventive controls at critical points throughout the system. Another comment contended that mandatory microbiological analysis of foods would be inappropriate because: (1) Statistically valid sampling programs for pathogens are not economically feasible because of the low incidence of pathogens in most foods; (2) the use of indicator organisms to predict the presence of pathogens is not always reliable and, where it is not, can become merely a test for aesthetics; and (3) microbiological analysis of foods is often costly, imprecise, and slow, and, therefore, not suitable for real time data generation.

The agency acknowledges the shortcomings of product testing, especially microbiological testing, used for process control as pointed out by the comments. The NACMCF, in its comments in response to FDA's questions about product testing, reiterated its view that, while verification is essential to the success of HACCP, end-product testing has limited value for measuring the success of a HACCP system. Comments also noted that in-process or finished product testing should not normally be a prerequisite for lot release under a HACCP program.

However, FDA recognizes that many processors will find that product testing has a role to play in the verification of HACCP systems, and the agency wishes to encourage incorporation of testing into HACCP plans, where appropriate. Consequently, the regulations at § 123.8(a)(2)(iii) list end-product and in-process testing as a verification activity at the option of the processor.

The agency provided guidance concerning appropriate attributes for product testing in the draft Guide and intends to elaborate on it in the first edition of the Guide.

6. Records Review

Section § 123.8(a)(3) requires that a trained individual review all records that document monitoring of CCP's, the taking of corrective actions, the calibrating of any process control instruments, and the performing of any end-product or in-process testing. The review of HACCP records by a trained individual was included in the proposed regulations at § 123.8(b). In response to comments that urged consistency with the recommendations of the NACMCF, FDA has designated this review a verification function for purposes of the final regulations and has included it in the section on verification. Specifically, the proposed regulations provided that a HACCP-trained individual review the monitoring records, sanitation control records, and corrective action records before distribution of the product to which the records relate. Under the proposal, the individual's review would include records of process monitoring instrument calibration, because the agency characterized these records as monitoring records.

The comments that FDA received on these provisions focused on the proposed requirement that the review by the trained individual occur before the product could be shipped. Several comments objected, stating that such a review before shipment was unnecessary, because under the corrective action provisions of the proposed regulation, any CL deviation caught by the observer/operator would necessitate the segregation and holding of the affected product before shipment until the safety of the product could be assured. One comment further stated that linking lot release to record review before shipment underestimates the level of control attainable through the monitoring and corrective action principles of HACCP.

Comments from several processors and trade associations stated that, for some processors, it would be impractical to withhold the shipment of every lot until HACCP records could be verified and signed. These comments noted that, with the use of today's high speed processing lines, it is normal practice for some processors to begin shipping products before the end of the shift (lot). Several comments also stated that holding a product until the HACCP records could be reviewed could result in a product being subjected to unfavorable conditions during storage, which could compromise both quality and safety.

Several comments urged that processors be permitted to review the HACCP records at the end of the day or at the end of the shift, even if this review occurred after distribution. Others suggested that record review should be performed within a ''reasonable time'' of production of the record.

The agency remains convinced that the coupling of lot release with verification-type record review provides a valuable added level of safety assurance. This kind of record review before shipment is a regulatory requirement for low-acid canned foods and acidified foods. FDA's experience with these industries is that record review before distribution has been instrumental in preventing the introduction of potentially hazardous foods into commerce (Ref. 221). The agency encourages processors to institute such a program whenever possible.

However, FDA accepts from the comments that the proposed requirement would cause certain processors to delay shipping perishable products and thus present an unacceptable burden to them. The agency therefore is not requiring that record review occur before shipment.

Uncoupling record review from lot release leaves as the primary purpose for record review the periodic verification that the HACCP plan is appropriate and is being properly implemented. Record review needs to occur with sufficient frequency so as to ensure that any problems in the design and implementation of the HACCP plan are uncovered promptly and to facilitate prompt modifications. The concept is roughly that of a ''feedback loop,'' with information coming out of the record review process in such a timely manner that it can have impact on the production of subsequent lots of the product.

FDA is convinced that a weekly review of HACCP monitoring and corrective action records would provide the industry with the necessary flexibility to handle highly perishable commodities without interruption, while still facilitating speedy feedback of information. FDA is reluctant to allow the level of flexibility provided by such language as ''reasonable time,'' out of concern for the confusion that it