on the relevant CL (e.g., flow rate, temperature, source of raw materials); temporarily diverting product around a point in the process at which problems are being encountered; or temporarily stopping production until the problem can be corrected.

Section 123.7(c) describes the steps that a processor must take whenever there is a deviation from a CL but no corrective action plan to follow. As stated above, these steps constitute a minimum generic-type corrective action plan. The objectives of these steps are the same as those of a preconceived plan: To ensure that adulterated product does not enter commerce and to correct the cause of the deviation. Because it is a generic-type plan that is intended to be applicable to any situation, some of the steps, such as segregating and holding the affected product (§ 123.7(c)(1)), might not be necessary if the corrective action had been predetermined. This aspect of the generic-type plan may provide processors with an incentive to predetermine corrective actions whenever practical.

Another such incentive is the requirement, at § 123.7(c)(5), that the processor reassess the adequacy of its HACCP plan when a deviation occurs. This requirement does not exist where a corrective action plan exists. The reason for the distinction is that, on one hand, if a processor has assessed its process and decided that CL failures are likely to occur from time to time at particular points, those failures, when they occur, do not represent a failure of the plan but a foreseeable occurrence. On the other hand, if the processor has not made such an assessment, and a failure occurs, it is not possible to say what the failure means. The processor must assess whether the deviation is the result of a system-wide problem that is not being properly addressed by the plan or simply a failure that could be expected to occur in the normal course of things. The failure must be fully assessed, and if it represents a failure of the plan, the plan must be modified to reduce the risk of reoccurrence.

The agency is convinced that the corrective action approach contained in the final regulations (i.e., predetermined corrective action plans at the option of the processor) adheres to the principles of HACCP as recommended by NACMCF (Ref. 34, pp. 199–200) and will not result in undue burden, confusion, or trade difficulties. At the same time, these regulations will provide the flexibility needed to accommodate the varying levels of HACCP sophistication within the industry. FDA is satisfied that employee indecision in responding to CL deviations will not result in a public health problem in the absence of corrective action plans because the final regulations contain a set of well defined actions that are to be followed if a deviation occurs and no predetermined plan exists. The actions outlined in § 123.7(d) ensure that no unsafe product will enter commerce, and that a normalization of processing conditions will be effected as quickly as possible. While the agency sees merit in the argument that predetermined corrective action plans will, in many cases, be economically beneficial to a processor (e.g., minimize product loss and wasted effort), such economic factors will, in and of themselves, motivate processors to predetermine appropriate corrective actions, but they do not mean that the agency needs to require the adoption of predetermined plans.

71. A few comments recommended that FDA review corrective action plans for adequacy during, or in advance of, the first regulatory visit. This review, the comments asserted, would help to avoid a situation in which the processor takes a corrective action in conformance with its HACCP plan, but the agency later determines that the action was inadequate.

FDA agrees that these comments reflect a desirable ideal but must acknowledge that such a review ordinarily will not be feasible. If processors complete their HACCP plans, including any corrective action plans that they choose to develop, before the effective date of these regulations, they may be able to obtain a review of those plans as part of a routine FDA inspection.

In any event, the agency intends to review corrective action plans that a processor includes as part of its HACCP plan during routine regulatory inspections. Where the investigator finds a shortcoming in the corrective action plan, the investigator will discuss it with the processor. As with a failure to meet any other provision of these regulations, in determining its response to such a shortcoming, the agency will consider the totality of the situation and the likelihood that the shortcoming will have an adverse impact on the safety of the product. If a corrective action plan has not actually been used as of the time of the investigator's review, and as a consequence of its review the agency advises the processor that the corrective action plan needs to be improved, it is likely that FDA will advise the processor to follow the alternative procedure in these regulations until the upgrade occurs.

2. Assessing the Product for Safety

72. FDA received comments on specific aspects of the generic-type corrective action plan provided in proposed § 123.7(a). A significant number of comments opposed the provision that would have required an ''immediate'' safety assessment when a CL deviation occurs. One comment stated that, because an appropriately trained individual may not be immediately available to make a determination of the acceptability of the lot, the provision should be modified to require segregation and holding of the affected product until either a timely safety review by a properly trained individual has been completed, or a determination has been made that the appropriate predetermined corrective action plan has been followed. A number of other comments also suggested that the phrase ''immediate review'' be revised to ''timely review.'' One comment recommended that FDA specify a maximum amount of time in which to evaluate the product, for example within 24 hours. Another comment advised that FDA permit processors to cook or freeze fresh product involved in a CL deviation, until an evaluation can be completed.

FDA agrees that immediate review is not necessary. As long as the review occurs before the product is distributed, the public health will be sufficiently protected. Consequently, while § 123.7(c)(2) requires a review to determine the acceptability of the affected product for distribution, it does not require that the review be immediate, nor does it otherwise specify a timeframe for review. If there is a chance that the product is still fit for commerce, FDA expects that economic considerations will dictate the timing of the review. FDA agrees that, in many cases, it would be advantageous for a processor to cook or freeze a product pending results of a safety evaluation. The agency has no objection to such an action as long as the processor maintains the identity of, and its control over, the lot.

FDA has also modified § 123.7(c)(2) from the proposal to require that the review of the product be conducted by someone with adequate training or experience, although FDA is not tying adequate training to training in HACCP (see § 123.10) as it did in the proposal. FDA made this change because, as comments pointed out, a 3-day course in HACCP would not necessarily qualify someone to make many public health determinations of this nature. The basis for this modification is more fully