that inclusion of this information in the plan is necessary to underscore that a processor has an ongoing obligation to be sure that the verification steps that it has determined are necessary are readily ascertainable by the processor and its employees as well as by regulatory officials.

FDA proposed to require that HACCP plans provide for a recordkeeping system that documents the monitoring of CCP's. The proposed regulations also provided that the records must include the actual values obtained during monitoring and any consumer complaints that relate to the operation of CCP's or possible CL deviations. FDA has removed the latter provision, relating to consumer complaints, from § 123.6(c)(7). As explained above, these final regulations treat consumer complaints as verification tools rather than monitoring tools. Consequently, consumer complaints need not be included in a recordkeeping system that documents the monitoring of CCP's. A full discussion of issues relating to consumer complaints is presented in the ''Consumer Complaint'' section of this preamble.

6. Positive Versus Negative Recordkeeping

The preamble to the proposed regulations invited comment on whether it was necessary for the results of monitoring (i.e., the actual values) to be recorded regardless of whether a CL was met (positive recordkeeping), or whether it was only necessary to record information when a CL was not met (negative recordkeeping). The agency noted that negative recordkeeping is presumably less expensive than positive recordkeeping.

65. A substantial number of comments addressed this issue. Approximately two-thirds of these comments, including those from trade associations, processors, Federal, State, and foreign government agencies, consumer advocacy groups, and a professional society, supported requiring positive records. The remaining one-third of the comments that addressed this issue, from trade associations, processors, and Federal and State government agencies, argued that records should only be required when a CL deviation occurs, or that positive records should be required or encouraged, but that FDA should be granted access to only the negative records.

In general, the comments supporting the need for positive records recognized that monitoring records serve two major purposes: To facilitate the identification of trends that would lead to a loss of control if not caught in time and to document compliance with, or deviations from, CL's. Comments from a large processor and a trade association stated that, based on their extensive experience with HACCP, positive monitoring records provide a pattern of results and values that is much more meaningful than sporadic negative records alone. Several comments stated that positive recordkeeping facilitates the taking of corrective action before the CL's are exceeded.

Several comments stated that a provision that required only negative records would penalize the firms that already maintain records of all CCP observations. A few comments suggested that neither firm management nor FDA could verify that the monitoring procedures specified in a processor's HACCP plan are being carried out if only records of deviations from CL's are kept, because there would be no records to indicate that the other checks were actually being made. A comment from a consumer group further argued that allowing the use of negative records alone could create the opportunity for processors to limit their monitoring, because no records would be needed to demonstrate that such monitoring was performed.

Most comments that supported the use of negative records alone stated that positive recordkeeping and the review of positive records was overly burdensome for both the industry and the regulator. A few comments stated that positive records generate massive databases that disguise CL deviations, rather than illuminate them. No examples of this phenomenon were provided, however. One comment suggested that since FDA inspects most processors once a year or less, it is questionable whether the agency would be in a position to pick up trends in the data from a review of all the positive records that would be retained. Another comment stated that it is just as unrealistic to expect FDA investigators to review all positive records as it is for FDA to inspect all fish. A few comments argued that the sheer volume of the paperwork produced with positive recordkeeping would result in technical or clerical errors by processors that could result in products being deemed by FDA to be adulterated.

Several comments suggested that a system where CL deviations trigger remedial actions, which are properly documented, should be sufficient for FDA's verification purposes. One comment suggested that because processors can falsify positive records as well as negative records, FDA was mistaken if its motive for proposing to require positive records over negative records was to help prevent unscrupulous processors from circumventing the system. An additional comment supported limiting mandatory HACCP recordkeeping to negative records because FDA could not rule out the possibility that future court decisions or changes in FDA policy might permit the disclosure of HACCP records in FDA's possession, and negative recordkeeping would reduce a company's potential exposure.

FDA's reasons for proposing positive records match those in the comments that support these kinds of records. As the preamble to the proposed regulations noted, recordkeeping is the key to HACCP, enabling the processor and the regulator to see the operation through time. Negative records alone do not allow this assessment over time and do not provide assurance that the appropriate monitoring was even performed.

FDA cannot conclude from the comments that supported negative records that the burden of positive recordkeeping is excessive or otherwise outweighs the benefits. The agency acknowledges that a requirement for positive records may be more burdensome than one that only requires negative records. However, FDA received no new data on this issue. Positive recordkeeping can be extremely simple and need not take much longer to perform than the monitoring necessary to determine whether the process is in control (e.g., noting the temperature of a refrigerator in a logbook located next to the refrigerator). The agency is convinced that this minimal additional effort greatly increases the chances that a processor's HACCP program will be successful.

Based largely on FDA's experience with the positive recordkeeping requirements in the low-acid canned food and the acidified food industries, FDA does not agree that the volume of positive records that a system will generate will defeat the system by hiding CL deviations or trends toward such deviations. FDA's regulations at parts 113 and 114 require that these industries perform positive recordkeeping at identified CCP's. The industry itself requested this requirement.

FDA has found that these processors have no trouble making positive records, and that both the processors themselves and the regulators become adept at reviewing them and deriving benefits from them that would not have been available from negative records. These benefits have included being able to pinpoint with confidence when a