flow diagram, and performing a hazard analysis (Ref. 34, pp. 187–188). All but the last of these have been identified by NACMCF as the ''five preliminary steps'' of HACCP.

It was, and still is, the agency's belief that processors would benefit from a process that included these five steps as well as a hazard analysis in order to successfully arrive at an appropriate HACCP plan. Nonetheless, the agency did not propose to require adherence to the ''five preliminary steps,'' or explicitly propose to require that a hazard analysis be performed. So long as the processor had, in the end, a HACCP system that was appropriate for species and process, and was being implemented effectively, the agency tentatively concluded that these regulations did not need to manage the process any further.

53. A number of the comments contended that FDA should require that firms adhere to these procedures in preparing a HACCP plan. Specifically, a few comments argued that the proposed rule significantly diminished the potential effectiveness of HACCP by not requiring that processors engage in the ''five preliminary steps.'' The comments argued that inclusion of the preliminary steps would facilitate international trade and reduce confusion on the part of seafood importers and exporters through consistency with an internationally recognized standard for HACCP.

Several other comments urged that the NACMCF recommendation for the development of a process flow diagram, in particular, by a processor be made mandatory. These comments identified several benefits from such a requirement: To facilitate employee implementation of the plan, to facilitate processor verification activities, to reduce the time needed for regulators to review the manufacturing process, and to enable the regulator to determine whether the processor properly considered the entire manufacturing process. One comment stated that FDA's assumption that flow diagrams are burdensome or unnecessary is contrary to the 1992 NACMCF Report which notes that flow diagrams could be simple representations that accurately depict the steps in a process, rather than detailed, technical drawings.

FDA acknowledges that, for the reasons stated in the comments, many processors will find that the development of a flow diagram is a useful preliminary step to the preparation of a HACCP plan. Other processors may find, however, that, because of the simplicity of their operations, the preparation of a written flow diagram is an unnecessary step. In either case, FDA is convinced that a processor's decision to develop or not to develop a flow diagram will be, and should be, driven by its perception of the benefits of doing so. The comments received on this subject were not sufficiently persuasive for the agency to conclude that a flow diagram should be made mandatory. The comments provided no basis to find that in the absence of a flow diagram, a processor could not properly develop a HACCP plan, or that a plan, so developed, would likely cause the HACCP program to fail.

As some of the comments pointed out, there may be some benefit to the regulator to have access to a flow diagram during an inspection, but this convenience is not a sufficient reason to mandate it. FDA investigators will likely develop their own flow diagrams during their in-plant inspections and compare them with the decisions reached by the processor in the development of the HACCP plan (e.g., the identification of hazards and CCP's). While it may be beneficial for the investigator to be able to compare his or her flow diagram with that of the processor, it is not essential to the conduct of the inspection.

FDA agrees with the comments that stated that the other four elements of the ''five preliminary steps'' are desirable attributes of the HACCP development process. However, the agency has not been persuaded that, in the absence of a regulatory requirement that they be followed, the HACCP program is unlikely to succeed. In order to write an appropriate plan some or all of these steps will likely have to be performed, even without a regulatory requirement to do so. However, if a processor can write a plan without these steps, the goals of the regulations will still have been met. For FDA to require them to be performed and documented in every case would add burden and reduce flexibility unnecessarily. Moreover, FDA is unconvinced that any inhibition to foreign trade is likely to occur if adherence to these steps is not required. FDA believes that foreign trading partners will be satisfied by the presence of a successful HACCP system and will not reject U.S. exports because steps preliminary to HACCP were not documented.

Even without a requirement mandating specific preliminary steps, FDA believes that most processors will follow the spirit, if not the exact letter, of the recommended procedures. These procedures provide the processor with a recognized method of plan development that will help lead to a successful outcome. FDA is primarily interested in that outcome. The NACMCF recommendation for the assembly of a HACCP team, in particular, could be a significant burden for the many small businesses operating in the seafood industry. For these reasons, the final regulations do not mandate any preliminary steps that processors must perform as a prerequisite to conducting a hazard analysis or drafting a HACCP plan.

2. Conducting a Hazard Analysis

54. A number of comments from trade associations and processors objected to the requirement in the proposal that every processor have and implement a written HACCP plan. These comments contended that FDA should revise this provision to require that a processor first conduct a hazard analysis to determine whether any food safety hazards exist that can be controlled through HACCP and then prepare and implement a HACCP plan only when the hazard analysis identifies at least one such food safety hazard. One comment stated that conducting a hazard analysis is the first step in a two-step process, with developing a HACCP plan being the second step. The comments urged consistency with the NACMCF recommendations in this regard.

FDA agrees with the approach suggested by the comments and believes that it is essentially consistent with what the agency proposed. Although FDA did not explicitly propose to require that every processor conduct a hazard analysis, completion of such an analysis by every processor was implicit in the requirement in proposed § 123.6(b)(1) and (b)(2) that processors identify both the hazards that are reasonably likely to occur and the CCP's for each of these hazards.

In response to the comments, FDA has decided to clarify its regulations to make the requirement that a hazard analysis be conducted explicit rather than implicit in order to clarify the steps that are required as part of a HACCP system. Moreover, this change allows the agency to make clear that conducting the analysis may or may not lead to the preparation of a HACCP plan.

Thus, FDA is providing in § 123.6(a) that processors shall conduct a hazard analysis or have one conducted on their behalf. It is the agency's expectation that most seafood processors will, after performing a hazard analysis, find it necessary to control for at least one hazard and, therefore, be obligated to prepare a HACCP plan. However, when no hazard is reasonably likely to occur, there is no reason to prepare a HACCP plan. Therefore, § 123.6(b) states, in