addressed two broad issues: Whether consumer complaints are relevant to a HACCP system, and if they are relevant, how they should be used. The question of whether FDA should have access to consumer complaints was a significant concern that comments found germane to both issues. Approximately one-fifth of the comments supported the proposed system or a variant of the system (i.e., they believed that consumer complaints are relevant to a HACCP system). Some of those who voiced general support urged more comprehensive agency access to consumer complaints, and others urged that some restriction on agency access be put in place. The remaining approximately four-fifths of the comments, principally from seafood and other food processors and trade associations, argued that consumer complaints have no place in a HACCP system.

Those comments that opposed the mandatory use of consumer complaints in a HACCP system provided a variety of reasons. The comments argued that consumer complaints are generally: (1) Unrelated to the safety of the product; (2) not received in a timely manner that would facilitate control of the process and are, in this way, akin to finished product testing; (3) erroneous and sometimes exaggerated or fraudulent; (4) vague; (5) subjective and nonscientific; (6) associated with hazards that develop during transportation, storage, and retail marketing, rather than processing, if they identify food safety hazards of any kind; (7) not traceable to a specific processing plant or lot of product; and (8) not readily associated with a specific CCP or CL failure, even where it is likely that they are the result of a problem during processing. These comments asserted that, therefore, consumer complaints are not an appropriate monitoring tool.

A number of these comments suggested that, given the problems listed above, sorting through the large volume of consumer complaints that are received by most large firms to identify those few that might be able to be linked to the performance of a specific CCP would be a waste of both the processor's and the agency's time. These comments stated that such a review of consumer complaints would divert their efforts from more productive tasks.

Several comments raised additional questions about consumer complaints as a HACCP verification tool. They suggested that there are better, more effective means of verifying that the HACCP plan is working properly. These suggestions are covered in the ''Verification'' section of this preamble. These comments further argued that consumer complaints are not identified in the NACMCF recommendations as a useful verification tool.

A relatively small, diverse group of comments, including those from a seafood processor, a seafood trade association, a State regulatory agency, an individual, and a professional organization, supported the handling of consumer complaints as proposed. One of these comments suggested that consumer complaints could be useful in FDA's efforts to verify that processors' HACCP programs are effective.

Another group of comments, from consumer advocacy organizations and a State regulatory agency, agreed that consumer complaints are an appropriate part of HACCP. One of the comments noted that the consumer performs the final quality control check, and that if a consumer finds a problem egregious enough to take the time to write a letter, the information contained in that letter should be considered in any evaluation of the adequacy of the relevant HACCP plan. The comment further argued that consumer complaints could bring to light unidentified CCP's. This benefit, the comment contended, would not be possible under the proposed regulations because the agency limited consumer complaints in a HACCP system to those that may be related to a CL deviation at an existing CCP. Finally, one of the comments noted that the inclusion of consumer complaint access in the proposed regulations is the one area in which the agency delivers on its ''water to table'' commitment.

FDA is persuaded that consumer complaints generally will not make an effective monitoring tool in a HACCP system, primarily because they tend not to provide the kind of immediate, reliable feedback expected of a HACCP-monitoring system. FDA agrees with the comments that suggested that monitoring procedures under HACCP must provide the processor with immediate feedback on whether the process is under control and be scientifically sound.

FDA is not persuaded, however, that consumer complaints are irrelevant to HACCP systems. The agency received no comments that were able to demonstrate that outside sources of information should not, where appropriate, supplement a processor's own monitoring as a way of determining whether the process is in control. Moreover, a number of comments stated that they go to some lengths to examine the consumer complaints that they receive. The question, then, is whether consumer complaints can serve some legitimate verification purpose in a HACCP system.

While consumer complaints are not specifically addressed in the NACMCF HACCP recommendations, the verification portion of that document states, in part, that verification inspections should be conducted, ''When foods produced have been implicated as a vehicle of foodborne disease.'' This statement is a recognition that information from sources outside the processing plant can and should be considered in the verification of a HACCP plan. In fact, it is FDA's experience that consumer injury or illness complaints to the agency occasionally point out problems traceable to defective controls at the food processing facility (Ref. 207). Where information that has potential relevance to food safety is available to a processor as a result of its own consumer complaint system, it is entirely appropriate for the processor to consider that information in assessing the adequacy of its HACCP program. FDA accepts the possibility that many, if not most, consumer complaints that a processor receives will not be germane to safety, that many will turn out not to be valid, and that others will relate to events at retail or that are otherwise beyond the ability of the processor to control. Nonetheless, FDA strongly believes—and the comments support this view—that a responsible processor will at least review consumer complaints to determine their potential value and take steps to correct the product or the process, when such stops are warranted.

FDA has concluded, therefore, that processors should evaluate the consumer complaints that they receive to determine whether the complaints relate to the performance of CCP's, or reveal the existence of unidentified CCP's, as part of their HACCP verification procedures. The agency acknowledges that the absence of consumer complaints does not, by itself, verify the adequacy of a HACCP system. However, after taking into account all the concerns raised by the comments, the agency is of the view that those consumer complaints that a processor does receive, and that allege a safety problem, can be of value as a verification tool and should serve that purpose. This conclusion is reflected in the requirements of § 123.8 of these final regulations (see discussion in the ''Verification'' section of this preamble), which lists the review of consumer complaints as an appropriate verification activity (§ 123.8(a)(2)(i)).

As explained earlier in this preamble, because the agency regards consumer