With regard to the comparison made by comments that FDA is requiring control of parasites in raw fish but not pathogens in raw fish, the characterization of FDA's policy towards pathogens is inaccurate. The sanitation provisions of these regulations are designed, in large part, to minimize the presence of pathogens in fish and fishery products, whether they are raw or further processed. The major opportunity for the introduction of enteric pathogens to processed fish and fishery products is from the processing environment as a result of insanitary practices rather than by the carcass of the animal (Refs. 3, p. 267; and 7, p. 33). For this reason, sanitation controls designed to prevent contamination of fish flesh are important to minimize the levels of enteric pathogens found on processed fish (Refs. 3, p. 10; 7, p. 27; 204; and 205). The agency is convinced that, if followed, these controls will be effective in minimizing the presence of such pathogens. Moreover, FDA has long enforced a zero tolerance for the presence of *Salmonella* on raw fish, based, in part, on the avoidability of such contamination through the application of CGMP's.

63. One comment stated that the term ''physical hazards'' in the proposal could be interpreted to include nonsafety related hazards.

In § 123.6(c), physical hazards are one of nine listed causes of ''food safety hazards'' that processors should consider for listing in their HACCP plans (§ 123.6(c)(1)(ix)). Thus, the agency believes that the language of this section clearly applies to food safety hazards only, and no modification of the provision is necessary in response to this comment.

FDA proposed that HACCP plans include the CL's that must be met at each CCP. FDA received no significant comment on this section (§ 123.6(c)(3)) and has made no substantive changes to it.

FDA proposed to require that HACCP plans include the procedures for both ''monitoring'' and ''controlling'' the CCP's. FDA recognizes that monitoring and controlling serve different purposes, and that the appropriate HACCP principle is the monitoring of CCP's to ensure conformance with the CL (Ref. 34, p. 197). How a processor exercises control is not critical to product safety so long as the CL is not exceeded. There are many ways to maintain control. No one way or list of ways needs to be stated in the plan so long as monitoring is taking place at an appropriate frequency to ensure that control is occurring and to detect CL deviations when they occur. For this reason, FDA has modified § 123.6(c)(4) to read, ''(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.''

FDA has also eliminated the reference in § 123.6(c)(4) to consumer complaints as a monitoring tool. As explained in more detail in the ''Consumer Complaints'' section of this preamble, FDA has concluded in response to comments that consumer complaints generally do not provide the processor with the kind of immediate feedback about whether the process is under control that monitoring should provide in a HACCP system. Consumer complaints may provide the processor with information that would be useful for verification purposes, however. These regulations therefore require processors to take consumer complaints into account as verification tools (§ 123.8(a)(2)(ii).

Likewise, FDA has moved the reference in the proposed regulations to the calibration of process monitoring instruments to the new ''Verification'' section of these regulations (§ 123.8), and it has eliminated the specific reference to computer software validation. As explained in more detail in the ''Verification'' section of this preamble, FDA has concluded in response to comments that calibration is a verification function that provides the processor with information about whether its monitoring equipment is functioning properly. Computer software validation is a form of calibration and need not be addressed separately in these regulations.

64. In the preamble to the proposed regulations, FDA asked for comment on whether guarantees from suppliers should be considered as an acceptable way of meeting the proposed monitoring requirement. Comments from a number of processors responded that a certificate from a producer that a lot of raw material fish is free from unacceptable levels of pesticide and drug residues should be an acceptable means of monitoring the hazards of animal drug and pesticide residues in aquaculture-raised fish. The comment held that reliance on suppliers' certificates may be necessary because of the logistical problems that could be associated with analyzing raw materials for pesticides and drug residues. Of particular concern, the comments said, is the time necessary to analyze the samples. The comments further stated that the certificates should be based on participation in an industry-wide quality assurance program designed to ensure that the raw materials are free from these hazards.

FDA believes that caution is warranted on the subject of supplier guarantees. Where more direct controls are available, they should be used. In the case of aquaculture-raised fish, more definitive controls than the acceptance of a certificate attesting to the absence of unapproved drug residues alone are available to a processor, and these controls are not unduly burdensome. They include the review of the supplier's animal drug control records when the lot is offered for sale and a system of onsite audits of the supplier, either by the processor or by a third party. Such alternatives are also available for most raw material hazards (e.g., checking container tags and harvester licenses as a means of controlling microbiological contamination in molluscan shellfish, and checking vessel storage records as a means of controlling histamine development in scombroid species). However, the agency recognizes that there may be some instances in which such controls are not possible, and suppliers' certificates or guarantees are the only available monitoring tool. In those cases, verification of the effectiveness of the certificates may be critical. Thus, the extent to which suppliers' guarantees can be relied upon will have to be considered on a case-by-case basis. However, FDA has made no change in § 123.6(c)(4) in response to the comments.

FDA has added § 123.6(c)(5) that describes requirements of the HACCP plan with regard to corrective actions. As explained in more detail in the ''Corrective Actions'' section of this preamble, FDA has concluded in response to comments that these regulations should provide the processor with the option of predetermining corrective actions. Predetermined corrective action procedures have the potential to enable a processor to take faster action when a deviation occurs than would be possible in the absence of such procedures, and to make a more timely response to the deviation when trained or otherwise qualified individuals are not readily available.

FDA has also added § 123.6(c)(6), which describes the requirements of the HACCP plan with regard to verification. As explained in more detail in the ''Verification'' section of this preamble, FDA has concluded in response to comments that a processor needs to specifically include in its HACCP plan the verification procedures that it will use and the frequency with which it will use those procedures. FDA finds