occur in all circumstances, the agency has modified the language in this provision to read in part, ''Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:'' (the list of nine categories follows in the text).

The Guide is not intended as a definitive list of the hazards that are reasonably likely to occur, under all conditions, for those species and processing methods listed.

HACCP is a operation-specific process. For this reason, the processor must decide on a case-by-case basis what hazards it needs to address; that is, what hazards are reasonably likely to occur. The purpose of the hazards portion of the Guide is to provide a listing of hazards, by fish species and by finished product type, that FDA knows to have a reasonable potential for occurrence in the product.

FDA encourages processors to use the Guide, as well as any other available information, to decide what hazards need to be addressed in any particular plan. Processors need to recognize that they need to use judgment in applying the Guide to their own particular circumstances. For example, a processor of one species of fish may find that pesticide contamination is listed as a hazard for the species, but may be aware of credible data that demonstrate that the water from which it obtains its fish is free of such contamination. In that case, the processor is free to deviate from the guidance. FDA intends to clarify the Guide on this point by distinguishing between hazards that are reasonably likely to occur all of the time (e.g., histamine in species that are prone to it) and hazards that are reasonably likely to occur under certain circumstances (e.g., certain toxins when a ''bloom'' is occurring).

5. The Plan: Specific Considerations

59. FDA proposed that HACCP plans be specific to each processing location and to each kind of fish and fishery product processed by a processor, except that the plan may group kinds of fish and fishery products together if the hazards, CCP's, CL's, and procedures required to be included in the plan are identical. A few comments from processors and trade associations suggested that production methods should also be allowed to be grouped together so long as the hazards and the control procedures for the production methods are identical. The comments suggested that grouping would reduce the paperwork burden on some processors without altering the benefits attainable through HACCP.

FDA agrees with the suggestion for the reason presented by the comments and has modified § 123.6(b) accordingly, to read, in part:

> A HACCP plan shall be specific to: (1) Each location where fish and fishery products are processed by that processor; and (2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

60. In the proposal, FDA specified that a HACCP plan must identify: The applicable food safety hazards; the CCP's; the CL's; the control and monitoring procedures; and the recordkeeping procedures. A few comments suggested that FDA use the word ''list'' or ''include'' rather than ''identify'' to describe a requirement for an item to appear in the HACCP plan. The comments suggested that it is not clear from the word ''identify'' whether the regulations are intended to require that the plan contain or include the actual values (e.g., the temperature of a refrigerator) or a description of the procedures, or whether it is permissible simply to make reference to their existence in a guideline or other source.

FDA's intent is that a HACCP plan explicitly include the value or a description of the procedures for each of the required HACCP elements. FDA agrees that a word such as ''list'' would be less ambiguous. Therefore, FDA has revised § 123.6 (c)(1), (c)(2), (c)(3), and (c)(4) by substituting the word ''list'' where the word ''identify'' appeared in the proposed regulations.

FDA has also revised § 123.6(c) by making another clarifying change. The agency has added the phrase ''at a minimum'' to the introductory statement to make clear that the required plan contents do not restrict a processor from including additional information in the plan, where it may be appropriate.

61. Two comments requested that FDA specify that decomposition, listed as one of the hazard categories in the proposal, is a hazard only in scombroid toxin-forming species.

These comments stated that decomposition in other species is not a safety hazard but is an economic and aesthetic problem.

FDA agrees with the comments in part. FDA's intent was to require control of decomposition in a HACCP plan only when it represents a food safety hazard. As described in the preamble to the proposed regulations, histamine (scombroid toxin) development as a result of microbiological decomposition in certain species of fish is a well recognized food safety hazard (Ref. 5, p. 24). There are some early indications, however, that the development of putrescine and cadaverine, also byproducts of decomposition of fish, under certain circumstances, may also represent food safety hazards (Ref. 203, p. 240). For this reason, FDA is hesitant to limit the safety concern associated with decomposition to the production of histamine. Accordingly, FDA has modified § 123.6(c)(1)(vi) to read, ''Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition.''

62. Comments from two State government agencies and a trade association stated that FDA should eliminate parasites as a safety hazard that must be considered for inclusion in a processor's HACCP plan. The comments noted that, with respect to pathogens, FDA makes the assumption that raw fish will be further processed by cooking, and that, therefore, that the pathogens will be destroyed and not pose a health hazard. The comments urged that the same rationale be applied to raw fish that may contain parasites. The comments further suggested that the retail level is appropriate point of control for parasites, and that the provisions of the Food Code are adequate to address this issue.

The comments further argued that parasites pose a hazard only in certain species that are consumed raw, and that mandatory control procedures for all fish that are consumed raw would create an enormous economic hardship for some segments of the industry. In particular, one of the comments contended that parasites have never been a problem in the large tunas that are eaten raw, and that it should not be necessary to freeze such fish before they are sold for raw consumption.

FDA's intent is to require control of parasites in a HACCP plan only in those instances when parasites are reasonably likely to occur in the portion of the flesh that is consumed, and the presence of the parasites will present a food safety hazard (e.g., where the fish is offered for raw consumption). To clarify this intent, FDA has modified § 123.6(c)(1)(vii) to read:

> Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to remove the hazard, or where the processor represents, labels, or intends for the product to be so consumed.