food safety hazard, and there has been no diminution of control of acute hazards as a result. Moreover, the agency is convinced that when determining, in accordance with § 123.6(a), what contaminant hazards are ''reasonably likely'' to occur in a particular type of product, most processors will have very few, if any, of these chronic exposure-type hazards to manage through HACCP as opposed to through some other method of control.

FDA intends to monitor the progress of the seafood HACCP program to judge, among other things, whether the application of HACCP to food safety hazards generally, rather than to the most extreme acute hazards, overloads the HACCP system and dilutes its effectiveness for all hazards. Until such an effect is actually found to occur, FDA is persuaded that the systematic application of preventive controls to food safety hazards generally will provide the American consumers with the most effective and efficient food safety system that has been devised to date. If FDA were to determine that HACCP needs to be scaled back in order to make it work, the agency will take appropriate steps to make such a change.

One other factor bears mention in this regard. FDA has long been aware of consumer concern about environmental contaminants in fish and fishery products. As previously mentioned, this concern was expressed in the comments to the proposed regulations. The chance that these regulations will increase consumer confidence in the safety of seafood products would be greatly diminished if these regulations did not require processors to consider the risks from these contaminants as part of their hazard analysis.

56. A comment from a trade association stated that, while there is potential for an unapproved direct or indirect food or color additive to be a health hazard, the use of an additive that has not been listed for use in fish but is routinely used throughout the food industry would not necessarily be likely to cause harm to human health. The comment said that a control for use of the additive should not be required to be included in a HACCP plan.

Under the act, certain products, such as food additives, new animal drugs, including new animal drugs intended for use in aquaculture, and pesticides, require premarket approval before they may be legally used. Moreover, this approval can be limited so that the product may only be used legally on or with specific foods, or for specific purposes, for which approval has been obtained. This limitation reflects a longstanding realization that the safety of these types of products is variable and must be established on a use-by-use basis. Whether an additive, drug, or pesticide is safe for a particular use, in a particular food, at a particular level, depends on factors such as the amount of the food that is consumed and, if the additive, drug, or pesticide is ingested in a living animal before capture, how the product is metabolized in that animal.

Therefore, a food additive that has been approved for use in some foods, but not fish and fishery products, is deemed by the act to be unsafe for use with fish and fishery products. FDA is not in a position to change this aspect of the law through regulations. Consequently, the agency has not created an exemption from the requirement for HACCP controls for safety hazards caused by the presence of unapproved additives or other products that lack premarket approval for fish or fishery products.

The agency is aware that it is possible that some of these products may pose no meaningful risk in fish and fishery products at levels approved or allowed in other foods. It is the obligation of the proponent of the use of the substance to follow applicable statutory procedure to establish this fact to FDA's satisfaction.

57. In the preamble to the proposed regulation, FDA specifically invited comment on whether, in order to reduce the burden of HACCP on the industry, as in the Canadian fishery products HACCP regulation, the agency should limit its HACCP approach to cover only those hazards that are introduced within the confines of the processing plant. This type of limitation would eliminate mandatory control of environmental hazards such as pesticides, natural toxins, industrial contaminants, and aquaculture drugs through the HACCP system.

One comment contended that a processor of fishery products would be in a difficult position attempting to exercise control over problems that occur during harvesting. The comment stated that the purpose of HACCP is to require that each processor be responsible for minimizing those serious hazards that it is in the best position to control, but that the proposed regulations would force the processor to take responsibility for hazards that it may be poorly suited to control. The comment argued that FDA's intent was to deploy HACCP solely as a way of reducing the agency's inspectional burden. The comment further stated that the focus should be on finding those few CCP's within a specific process where a serious hazard can best be controlled. Several other comments expressed confusion about the application of HACCP to environmental hazards.

The preamble to the proposed regulations described the link between environmental hazards, such as natural toxins (e.g., ciguatera toxin, domoic acid, and saxitoxin), histamine, and various viral and bacterial pathogens, and human disease. The NAS' ''Seafood Safety'' report (Ref. 7, p. 1) suggested that the most significant reduction in illness from seafood would come from the control of environmental hazards. To eliminate coverage of such hazards from these regulations would be to eliminate the greatest share of anticipated benefits.

The preamble to the proposed regulations provided a number of ways in which the processor can exercise control over environmental hazards. This control derives from the fact that responsible processors already exercise discretion in obtaining their raw materials. Control is achieved by checking tags on containers of molluscan shellfish to ensure that they are harvested only from approved waters, checking with fishermen to ensure that finfish do not originate from harvest areas that are closed due to the presence of excessive agricultural or industrial contaminants, and physically examining incoming histamine-forming species for evidence of decomposition and insisting that harvest vessels exercise control over the time and temperature of storage for these species. Similarly, processors of aquaculture-raised species can audit or otherwise insist on a producer controls over the use of animal drugs or other hazards resulting from inappropriate husbandry practices. In a HACCP system, these are examples of controls that can be applied at the first CCP, i.e., at the receipt of raw materials.

FDA concludes that the measures that a processor takes to ensure that its raw materials are free of environmental hazards are a critical part of a seafood HACCP program. Responsible processors already exercise the kind of control necessary to ensure that their raw materials do not present such a hazard. If a likely hazard exists, it would not be sufficient to use the price offered for raw materials to be the only measure to protect against the hazard.

For these reasons, FDA has retained environmental hazards in the list of food safety hazards that processors should consider in § 123.6(c)(1). To clarify that there are hazards that occur before receipt of raw materials that can be controlled nonetheless by examination or discretion at the