seafood consumption; and a reduction in the number of violative products that enter the marketplace. Several comments stated that periodic inspections of, and sampling at, processors and importers by FDA, State, and foreign officials, coupled with illness reporting from a strengthened CDC program, would provide adequate verification of the effectiveness of the program. However, two other comments stated that the success of the seafood HACCP program cannot be measured solely by a decrease in illnesses, because many food-borne illnesses are the result of problems in the retail sector, which is neither covered by these regulations nor adequately regulated by the States.

The agency agrees with those comments that suggested that the ultimate goal of these regulations should be the improved safety of fish and fishery products—a reduction in the actual number of seafood-related illnesses. FDA will continue to closely monitor the CDC system, as well as reports of illness and death attributable to the consumption of seafood that it receives from other sources, for trends that may indicate an emerging problem or the intensification or modification of an existing problem. However, the agency also agrees with those comments that suggested that, because many of the seafood-related illnesses are attributable to recreational or subsistence fishing or to problems in the retail and food-service sectors (Ref. 7, pp. 2; 15; 27; and 28), improvements in process controls that result from the implementation of HACCP may not be fully reflected by a reduction in the number of illnesses. Additionally, as has been previously discussed, the CDC system encompasses only reported illnesses and is an imperfect means of judging reductions in actual numbers of illnesses. FDA is supportive of a strengthening of the CDC reporting system.

Based in part on the comments received, the agency will be looking at ways to assess a relationship between success of the HACCP program and levels of consumer confidence, levels of violative product in the marketplace, improvements in the quality and quantity of preventive controls throughout the industry; and the results of FDA and cooperating State and foreign inspections. As indicated in the summary of the Regulatory Impact Analysis elsewhere in this preamble, FDA is planning to evaluate key features of this program within the first several years of implementation. This evaluation will include an assessment of its effectiveness.

169. One comment suggested that end-product testing should be used by FDA for program surveillance purposes, particularly for imports. This comment encouraged FDA to conduct statistically reliable baseline and monitoring surveys, modeled after those used in the MSSP, conducted by NMFS, to: (1) Determine how often consumer hazards occur; (2) set specific goals, objectives, and operational strategies for the HACCP program; and (3) provide a means by which the program's success can be measured.

FDA has historically collected and analyzed surveillance samples during and outside the course of its routine inspections. The purposes for these sample collections, in many ways, align with those suggested by the comment. The agency is committed to continued surveillance sampling and intends to use such sampling in an assessment of the HACCP program.

170. Another comment suggested that HACCP will only be successful in improving confidence in seafood if the program is accompanied by a consumer education effort that explains the benefits of HACCP. The comment encouraged FDA to perform a baseline study that assesses the level of consumer anxiety with respect to seafood consumption and compare it to the results of a study that it performs sometime in the future.

FDA agrees that another major goal of these regulations is to increase consumer confidence in the safety of seafood. The agency recognizes that publication and enforcement of regulations aimed at improving seafood safety alone will not achieve that goal. Consumers must be informed of the benefits of producing products under HACCP preventive controls. Within its budgetary constraints, the agency intends to engage in a program of consumer education for that purpose. The prospect of baseline and followup studies of consumer confidence (or anxiety) will also be considered.

P. Other Issues

FDA received a number of additional comments that did not address any specific provision of the proposal, although some of them were in response to invitations in the preamble to comment on various subjects.

1. Relationship to Other Programs

In the preamble to the proposed regulations, FDA invited comment on how FDA's HACCP program for seafood processors should mesh with existing State HACCP programs for seafood, in order to avoid imposing inconsistent Federal and State HACCP requirements. In the preamble, FDA acknowledged that many States are under considerable pressure to cut back on programs where there is an overlapping Federal program. Nonetheless, the agency urged States to maintain, if not strengthen, their seafood programs and to work with FDA to develop an integrated Federal/State, HACCP-based seafood control program.

171. Approximately 12 comments, representing processors, trade associations, and State government agencies, recommended that FDA coordinate its HACCP program with existing State and Federal seafood control programs. Several comments emphasized that a coordinated effort would ensure uniform application and interpretation of HACCP principles, while preventing duplication of effort that wastes limited enforcement resources. One comment stated that such a coordinated effort would be facilitated if only a single HACCP plan were required for each processing facility, rather than one that was designed to meet FDA requirements and another that would meet State requirements. Another comment noted that a multitude of differing HACCP regulations would only serve to confuse processors and dilute the effectiveness of the Federal program. The comment further recommended that FDA work with AFDO to promote State laws and regulations that are compatible with FDA's HACCP program.

One comment suggested the formation of a task force representing the food industry, FDA, USDA, and DOC to work towards the goal of reducing regulatory duplication.

The agency agrees that there is a need for Federal/State partnership to facilitate the efficient implementation of HACCP programs. FDA believes that coordination with the States would permit both the agency and the States to leverage their inspectional resources. FDA, as well as the States, would benefit by dividing the workload and sharing data and other information. Such coordination would also benefit industry through consistent inspections and regulatory requirements.

The agency has already begun to coordinate its efforts with the States on seafood. The formation of the Alliance, to which AFDO is a member, is one such endeavor. The Alliance is described in detail in the ''Training'' section of this preamble.

With FDA's support, AFDO passed a resolution supporting the development of FDA/State partnership agreements at its 1994 meeting in Portland, ME (Ref. 220). The resolution specifically recommended that HACCP be the basis of such partnerships and noted the