shared roles of FDA and State regulators in seafood safety, the limited resources of both levels of government, and the existence and the potential impact of the Alliance.

Meanwhile, FDA is increasing its use of partnership agreements with State enforcement agencies. For instance, the Northeast Region of FDA has entered into a threeway partnership agreement with the Northeast Food and Drug Officials Association and individual States to provide industry with HACCP training at the retail level. FDA also expects to enter into partnership agreements with States to implement HACCP pilot programs for foods other than seafood. FDA's Northeast Region has already signed such an agreement with the Commonwealth of Massachusetts, and more are anticipated.

These initiatives demonstrate the agency's desire to coordinate its efforts with the States. The agency's cooperative efforts in the area of HACCP reflect a trend. The agency has used cooperative efforts in other areas, such as pesticide sampling and workplan sharing. FDA will continue to explore ways to coordinate the Federal and State role in the regulation of seafood.

172. A number of comments recommended that States act as the primary enforcement agencies for these HACCP regulations, while FDA's responsibility would be to evaluate the States' compliance with HACCP inspection protocols. Some of these comments suggested that such a program could be patterned after the NSSP.

FDA is adopting these HACCP regulations to implement and enforce the act. While FDA plans to work cooperatively with the States in all ways possible, the agency cannot delegate its authority under the act. It is possible that in some aspects of seafood processing, the States will serve as the primary enforcement agencies, with FDA serving primarily an auditing function. However, responsibility for enforcing the act and these regulations must remain with FDA.

173. A number of comments, from processors, trade associations, and one consumer advocacy group, maintained that FDA's HACCP regulations should preempt any existing State HACCP programs. The comments contended that Federal preemption would ultimately reduce confusion caused by conflicting State programs, reduce costs, and promote uniformity. Examples of the specific areas of conflict were not provided by the comments.

As was previously stated, FDA intends to work through AFDO and through Federal/State partnerships to seek consistency in State regulatory approaches to HACCP for seafood inspection and through the NSSP process and the ISSC to attain this goal specifically for molluscan shellfish. Moreover, processors in each State must comply with Federal HACCP requirements if their product moves in interstate commerce. For these reasons, the agency has concluded that there is no need for Federal preemption of State regulatory requirements.

174. Several comments encouraged FDA to work closely with NMFS to coordinate FDA's program with the existing NMFS' HACCP program. The comments noted that cooperation with NMFS would help the two agencies avoid wasteful duplication of effort and would reduce the burden on those firms already operating under the NMFS program.

FDA agrees with these comments and notes that FDA and NMFS are coordinating their HACCP programs to ensure compatibility. Nonetheless, FDA advises that the NMFS program is a voluntary, fee-for-service program and is likely to continue to include features that go beyond the requirements of these regulations, especially in the area of preventive controls for economic fraud and plant and food hygiene.

A 1974 MOU between FDA and NMFS recognizes the respective roles of the two agencies and commits the two agencies to consistency and cooperation. FDA will continue to work with NMFS to maintain a coordinated Federal effort.

2. ''Whistleblower'' Protection

175. A few comments urged that these regulations include ''whistleblower'' protection for employees of seafood processors. Whistleblower protection is designed to protect workers from being fired or otherwise discriminated against for revealing wrongdoing by their employers. The wrongdoing in this case, presumably, would likely involve the falsification of HACCP records. The comments argued that: ''Whistleblowers are iispensable as the eyes and ears for overextended FDA personnel making limited spot checks. The public's line of defense will be no stronger than the shield protecting industry worker's rights to obey and help enforce this law.''

One concern that FDA has heard about the credibility of a HACCP system is that important records can be falsified. It is alleged that, without whistleblower protection, it is much less likely that the agency will know about falsifications.

While the agency is confident, based in part on its experience reviewing records in the low-acid canned food program, that it can detect falsification, FDA also expects from experience that it will be alerted to possible wrongdoing from time to time by employees of processors even in the absence of whistleblower protection. FDA has received, and acted upon, confidential information from employees of regulated firms for decades. This assistance has proven invaluable on many occasions. The only protection to these employees available from FDA has been confidentiality.

The question raised by the comments is whether, in addition to the actions against the product or the processor that would be available to FDA as a result of violations of the requirements of the act and these regulations, there must be specific protection for employees in order for the program to succeed. The agency has concluded that, like other FDA programs, this program can be successful in the absence of specific whistleblower protection, and that congressional action would be necessary to provide protection other than confidentiality.

FDA cannot provide whistleblower protection in these regulations. FDA believes—and case law bears out—that there must be a nexus between the conduct being required by regulations and the focus of the underlying statute, in this case primarily section 402(a)(4) of the act. An analysis of the application of section 402(a)(4) of the act to these regulations can be found in the ''Legal Basis'' section of this preamble.

While FDA has determined that an assessment of processing risks and a plan that ensures that these risks are minimized has the requisite nexus to section 402(a)(4) of the act, and that this nexus justifies adopting these regulations, the agency does not see a sufficient nexus between whistleblower protection and the prevention of adulteration of food. If a firm retaliates against an employee who brings complaints or other information about the firm to FDA, the implication of such an action is that there is a condition at the firm that may need investigation, not that the products produced by the firm are necessarily adulterated. It may be the case that the products are adulterated, but such a conclusion does not flow as directly from section 402(a)(4) of the act as does the conclusion that seafood products not produced under a HACCP plan have been produced under insanitary conditions whereby they may have been rendered injurious to health. For this reason, FDA concludes that it lacks