clearcut authority to provide whistleblower protection in these regulations.

3. Separation of Quality Control (QC) and Production

176. A few comments requested that the regulations mandate structural independence within a processing firm between ''HACCP QC [quality control] personnel'' and ''production'' personnel. Otherwise, according to the comments, ''HACCP QC personnel could still be hired and fired by a production supervisor.''

FDA does not believe that a change in the regulations would be beneficial in this regard. It is important to recognize that, under HACCP, production personnel are the observer/operators who perform the initial monitoring of CCP's as well as the recordkeeping that documents the results of this monitoring. The operation of the HACCP system must involve the whole organization, not just QC personnel.

However, it is reasonable to expect that, where practical, verification activities should be performed by individuals other than those who made the records in the first place. For verification, the agency encourages the kind of organizational separation that is being urged in the comments.

The agency recognizes, however, that many seafood companies will not be large enough to have distinct, independent organizational units that can verify each other's work. The seafood industry is characterized by small businesses. FDA has concluded that such a requirement is not practical for this industry.

It is worth noting that the regulations at parts 113 and 114 for low-acid canned foods and acidified foods contain recordkeeping requirements and some verification requirements that are similar to the provisions of these regulations. In certain respects, parts 113 and 114 served as models for the seafood HACCP program. Those regulations have succeeded even though they do not require a separation between QC personnel and production personnel. Given this history, the agency is reluctant to mandate the internal structure of seafood processors.

4. Education

177. FDA received a number of comments on the subject of seafood safety education. These comments were in response to an invitation in the preamble to the proposed regulations for comments on risk reduction activities that could be regarded as complementary to HACCP, primarily directed toward postprocessing handling. In addition, FDA asked for comment on appropriate education and information that should be directed toward consumers and recreational fishermen, even though education aimed at these groups is actually outside the scope of this rulemaking. FDA made this request based on a recognition that HACCP cannot reasonably be expected to solve every problem. The agency recognizes that HACCP must be integrated into a comprehensive program for seafood safety. Education is another important component of that program. As one comment noted:

> * * * the responsibility for seafood safety should be met at every level of seafood distribution, from harvesters to processors to retailers, restaurants and, finally, the consumers themselves. Regulations are not a substitute for informed and responsible behavior and it is impractical to extend the scope of the proposed regulations to everyone involved in handling and consuming seafood.

The comments overwhelmingly endorsed the value of education. They strongly supported education for: (1) Consumers on the handling and purchasing of seafood, especially through brochures at the point of purchase and information available at pharmacies, and on the significance of HACCP, especially with regard to the government's verification role; (2) recreational fishermen, provided by the State during licensure (with guidance from the Federal government) and through articles in popular fishing and outdoors magazines; (3) subsistence fishermen; (4) retailers, including food service and restaurants.

FDA greatly appreciates these comments. The agency agrees that education is an essential complementary activity to HACCP as well as to other aspects of FDA's overall seafood program. The comments will be taken into account as the agency develops its educational program.

178. FDA also invited comment on whether the agency should consider proposing to require handling instructions for consumers on the labeling of seafood. Any action that FDA were to take along these lines would be as part of a separate rulemaking.

The agency received about 20 comments on this issue. Approximately half of those comments supported the notion of mandatory safe handling instructions. One business noted that safe handling instructions would help to ensure the safety of a product through the distribution chain, while another business said that such instructions had a real potential to decrease seafood-related illness. One individual commented that safe handling instructions would increase consumer confidence in these products. One industry comment noted that a task force composed of industry, Federal and State agencies, and consumers should agree on the appropriate statement. Some comments indicated that safe handling instructions might be appropriate for high-risk products.

The remainder of the comments on this issue disagreed that safe handling instructions for seafood should be required by FDA. Many of these comments noted that most seafood products include such instructions voluntarily. One trade association commented that such a requirement would limit retailers' flexibility and creativity and impose significant new costs on retailers and consumers. Most of those comments noted that requiring new information would detract from other labeling requirements.

FDA appreciates these comments and the different points of view that they represent. The agency will use the comments in its deliberations on this issue.

179. Finally, FDA described some of its educational efforts aimed at medically compromised individuals about avoiding raw molluscan shellfish and invited comment on types of education and information activities that might be useful in this regard. The agency received about a dozen comments on this subject.

Most of these comments addressed whether there should be mandatory warning labeling for raw molluscan shellfish. A majority of the comments stated that the agency should require warning labeling. Three comments from consumer groups stressed the need to protect high-risk individuals. One State government commented that warnings for raw molluscan shellfish should be tied to specific locations and times of year. One professional association requested that the warning state that the shellfish should only be eaten if it is certified and tagged.

Three comments stated that warning labels would be inappropriate. One comment noted that shellfish are not consumed in enough quantity to be a problem. Another comment stated that warning labels would unduly alarm those not at risk and that better channels exist for educating those at risk.

A few comments did not specifically address warning labels but recommended that FDA target advice directly to compromised individuals. Those comments suggested that FDA direct information to the medical community involved in the treatment of those individuals.