Again, FDA thanks the comments for providing views on a matter that is outside the scope of this rulemaking. FDA is working to provide information to at-risk populations and its strategy on how best to do so is evolving. The agency will take the comments into account as it develops policy in this area.

In summary, 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 relating to education will be useful to the agency as it develops its education programs.

5. Traceback Mechanisms

180. One comment recommended that FDA develop and incorporate methods to trace back fish and mandate such traceback in these regulations. The comment described the use of bar codes and computer-based tracking numbers by a meat products company that enable it to trace a specific cut of meat from a store or restaurant to its source.

The agency acknowledges that traceback to the water would be useful for certain species of fish associated with certain hazards, e.g., ciguatoxin. On the other hand, traceback to the water for scombrotoxin would not be particularly useful, although traceback through the distribution chain to find out the source of mishandling would be useful. The agency urges the industry to consider this comment. FDA advises that it is willing to explore this idea further, although not as part of this rulemaking.

6. Tribal Governments

181. FDA received a few comments on the effect of these regulations on tribal governments. The preamble to the proposed regulations noted that Executive Order 12875 of October 26, 1993, requires, among other things, consultation with tribal governments before the formal promulgation of regulations containing unfunded Federal mandates. While FDA does not believe that these regulations impose an unfunded Federal mandate, the agency wishes to foster consultation on matters that might significantly affect tribal communities. Consequently, FDA requested comment on the economic effect of the regulations on tribal governments.

FDA received no comments from tribal governments. One comment, from a tribal business, stated that the impact of the regulations on tribal governments will be beneficial because they will result in safe products, positive consumer perceptions, and positive market impacts. The other comment that mentioned this subject was from an academic, who expressed the view that the regulations will have a major impact on tribal groups involved in fisheries and contains unfunded Federal mandates. The comment did not elaborate. Neither of these comments justifies any change in these regulations.

The agency remains interested in fostering consultation with tribal communities as they see fit and encourages correspondence from tribal governments.

7. HACCP System Improvements

182. A comment urged that there be a process to continually amend or update these regulations.

FDA points out that such a mechanism exists in its regulations. Under § 10.30 (21 CFR 10.30), interested persons are provided with a process by which they can petition the agency to amend and update these regulations.

From a less mechanistic viewpoint, the agency recognizes that these regulations represent a pioneering program that has not been attempted before. While the agency believes that sufficient groundwork has been laid to adopt these regulations and to begin to implement them, FDA also acknowledges that full scale implementation will reveal modifications that may be necessary, both in the short and long terms. Consequently, the agency will be highly receptive to feedback from all parties who are affected by these regulations and will remain open to changes that are necessary in the regulations. The ''Verification'' section of this preamble reflects the agency's interest in evaluating this program.

183. A number of comments asked for improvements in the foodborne-illness reporting system operated by CDC. Some comments urged collaboration between FDA and CDC. One comment advocated the creation of an active reporting system.

These comments are essentially outside the scope of this rulemaking. Nonetheless, the agency recognizes that the strength of the foodborne-illness reporting system bears directly on the ability of the agency to measure the public health impact of HACCP. Both FDA and CDC agree that underreporting is an undesirable feature of the current system. FDA and CDC have been collaborating on an active-type reporting system. The limiting factor, however, will always be resources. Significant improvements in the current system will involve considerable expense.

184. One comment provided views on factors that would limit the effectiveness of HACCP. The comment cited:

> [P]oor commitment by company management and lack of allocation of necessary resources; improper training; lack of understanding and planning in all stages of implementation of a plan[,] and failure to recognize the need to understand the corporate culture change which must accompany an effective HACCP program.

FDA agrees with this comment but hopes that company management will embrace HACCP and recognize the benefits that it offers to the firm.

III. Paperwork Reduction Act of 1995

This final rule contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collections are shown below along with an estimate of the annual recordkeeping and periodic reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Reporting and recordkeeping requirements for processors and importers of fish and fishery products under the provisions of 21 CFR parts 123 and 1240. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products.

Description: This regulation implements the use of Hazard Analysis and Critical Control Point (HACCP) methodology to ensure that processed and imported fish and fishery products are safe within the meaning of sections 402(a)(1) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and 342(a)(4)).

Description of Respondents: Businesses or other for profit organizations.

Although the January 28, 1994, proposed rule provided a 60 day comment period (extended to 90 days in the April 7, 1994, Federal Register, 59 FR 16578) under the Paperwork Reduction Act of 1980, and this final rule incorporates the comments received, as required by 44 U.S.C. section 3507(d), FDA is providing additional opportunities for public comment under the Paperwork Reduction Act of 1995, which applies to this final rule and was enacted after the expiration of the comment period.

Therefore, the agency solicits public comment on the information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper