illnesses occurs it is not always directly possible to relate the reported illnesses to risk. This subject is also discussed at length in the preambles to both the proposed and final rule.

One comment recommended that no firms be completely exempt, but that some firms be subject to different HACCP requirements depending on size. The smaller the firm, the less strict the record-keeping, testing, and monitoring requirements. The use of a short form for recordkeeping and informal monitoring was supported in some comments.

Again, this is a topic that is extensively covered in the preamble to the final rule. FDA notes that HACCP depends on the degree of risk and complexity of processing and that HACCP requirements for each plant are calibrated based on these factors. Whether the plant is large or small, if there are few hazards and simple processes, HACCP requirements are inherently minimal. If there are no hazards, no HACCP plan is required. Overall, however the agency believes that many smaller firms are associated with simpler processes and that the HACCP system already accommodates the commenter's concern.

In the long run, as processors adopt HACCP and attempt to pass costs on to consumers, the retail price of seafood will rise by less than 1 percent. In the absence of an increase in consumer demand that may result from this regulation, as the price of seafood rises, consumers will purchase less seafood. As producers fail to sell all of the seafood offered at the higher price, output must fall. Moreover, output must decrease in the highest cost sector of the industry, generally small processors. Although it is possible that small processors will cut back production but stay in business, the small profit margins of some small seafood producers strongly imply that the reduction in output will come about because small processors go out of business. For every one percent increase in the price of seafood, approximately 140 small processors could go out of business. The estimated number comes from the following calculation. FDA has estimated that as costs are passed on, HACCP will raise the price of seafood to consumers. The price elasticity of demand, which is the percentage change in quantity purchased divided by the percentage change in price, is estimated to be −0.37 for seafood (Ref. 227). A one percent increase in the price consumers pay for seafood should therefore reduce the quantity purchased by 0.37 percent (1 percent times −0.37). FDA believes that the entire reduction in output attributable to HACCP will be borne by small processors who go out of business. Although close to 80 percent of seafood processors are classified as small, small processors account for only 10 percent of total industry output (Ref. 228). In the case of a 0.37 percent decline in total processing output represents a decline in the output of small processors of 3.7 percent (0.37 percent divided by 0.10). If the decline in the number of processors were proportional to the decline in the output of small processors, the reduction in the number of processors would be 3.7 percent in the case of a 1 percent price increase. FDA is uncertain as to what price increase will actually occur.

The agency finds that the number of small seafood processors that go out of business will be determined by the cost per unit (or per plant) of implementing HACCP, the effect of HACCP on seafood prices, the ability of small plants to pass costs on to consumers, the current practices of the plants and the implementation time. The analysis has assumed that the regulation will have no positive effect on the demand for seafood. If the regulation in fact increases consumer confidence in seafood sufficiently to increase the demand for seafood, then the effect on small business would be less.

Although the economic impact on small firms is difficult to predict, many small firms should be able to implement HACCP at low cost, as they have already fulfilled many of its basic requirements. The closer a firm's current practices are to HACCP, the lower the cost of HACCP and the more likely is firm survival. Some small firms occupy market niches that allow them to pass on more of their costs than the industry average, increasing their likelihood of survival.

The effect of HACCP on small seafood processors depends on their costs of compliance and on the changes in the relative price of seafood. FDA expects the relative price increase attributable to HACCP to be small. For many small firms, the flexibility built into the regulation strongly implies that HACCP costs will be low. In consideration of small firms, the agency has extended the effective date to 2 years from publication. FDA will also be publishing a Guide that will provide small processors with valuable information for developing and implementing HACCP. Additionally, the agency, in cooperation with Sea Grant Universities and others through the Seafood HACCP Alliance, will be providing to small firms assistance on training and other needs.

FDA recognizes that HACCP is an innovative regulatory system that has not been applied on a large scale to ongoing commercial enterprises in the United States. For this reason all of the agency's estimates of firm behavior, costs and benefits necessarily involve substantial uncertainty. As explained in this Regulatory Impact Analysis, FDA has used modeling techniques and informed judgements rather than firm empirical data to estimate many effects. In order to determine the accuracy of these estimates, and also to assist in possible mid-course corrections, FDA and HHS plan to conduct an evaluation study during the first few years after the effective date of these regulations. This study could focus on each major type of one-time or continuing compliance cost, on different types of firms, on different sizes of firms (with particular attention to the smallest firms), and on both costs required by the regulation and on costs that firms may incur unnecessarily. It could also address the ability of firms to understand and implement HACCP properly, and any other problems that may impede rapid and inexpensive implementation. This study could also include an exploratory analysis of benefits, addressing both improvements in processing as measured by elimination of hazards and, to the extent permitted by existing data systems, early trends in reported incidence of illness caused by seafood.

V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (59 FR 4142, January 28, 1994). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment, and that an environmental impact statement is not required.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, ''Diet and Health: Implications for Reducing Chronic Disease Risk,'' National Academy Press, Washington, DC, 1989.

2. National Heart, Lung, and Blood Institute, DHHS, ''National Cholesterol Education Program: Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction, Executive Summary,'' NIH Publication No. 90–3047, National Institutes of Health, Bethesda, MD, 1990.