regulation, benefits could potentially be large.

However, FDA recognizes that there is also a short term cost (e.g., as molluscan shellfish harvesters attempt to supply processors with untagged shellfish or from vessels without sanitary facilities aboard and find the harvest rejected). The same will also be true for finfish which have not been properly temperature controlled from harvest to processor. These harvests will be discarded although this behavior is not expected to occur often, or more than once in any instance.

D. Costs and Benefits of Sanitation

A portion of the costs and benefits of this rule derive from the improvements in the facilities and CGMP's in seafood plants. Although all food manufacturing plants are required to produce food under sanitary conditions now, FDA's experience, and that of others, indicate that many seafood processors are not producing seafood under those conditions. The sanitation, monitoring, and recordkeeping provisions of this rule are expected to drive processors to improve their sanitation conditions and thus reduce the need for FDA to enforce CGMP's through regulatory actions. These provisions will produce net increases in societal welfare with accompanying costs and benefits.

Current goods manufacturing practices include such things as cleanliness and habits of personnel, the conditions of buildings and facilities, equipment, production and process controls, and conditions of warehousing and distribution of the product. It is difficult to differentiate between costs and benefits that are HACCP-related and those that are sanitation-related. For example, processors are required under HACCP to keep records that show that CGMP's such as ''Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act'' are being followed (see 21 CFR 110.80(a) (2) and (4)). However, the benefits derive from making plant and processing changes, uncovering problems in processing due to recordkeeping and taking corrective action which prevents hazardous seafood from being sold. Thus, HACCP and CGMP's are inextricably intertwined and it is difficult to calculate the marginal benefits and marginal costs of each.

E. Costs and Benefits Attributable to Foreign Governments

FDA has reported the portion of the increased costs that are expected to be passed on to U.S. consumers by foreign processors. The justification for this action is that FDA has not included safety benefits that foreign consumers may enjoy when foreign firms that export to the United States introduce HACCP into their plants. FDA has also included, as a benefit of this regulation, reduced enforcement actions toward products produced by foreign firms and reduced illnesses that U.S. consumers suffer from imported seafood.

In a benefit-cost analysis, costs and benefits are attributable to choices made among competing options. However, in this rule, there are difficulties in assigning the costs and benefits to choices made by FDA to require HACCP of domestic and foreign seafood processors. This difficulty arises because other countries either already require HACCP or have indicated that they will do so in the near future—for both their domestic and imported seafood products. No costs or benefits should be ascribed to choices made by the U.S. Government in this rule that affect firms already complying with foreign regulations, if the regulations are the same and no changes need to be made to be in compliance with the U.S. regulation.

Thus, foreign firms in those countries who export to the United States may be required to comply first with the U.S. plan or first with their own country's plan; the timing is impossible to predict. However, FDA does have evidence from the European Union that the seafood produced by the following countries (at least seafood for export) have met the EU standard for HACCP— Albania, Australia, Austria, Belgium, Brazil, Canada, Chile, Columbia, Denmark, Ecuador, England, Faro Is., Finland, France, Germany, Greece, Holland, Iceland, Indonesia, Ireland, Italy, Japan, Luxembourg, Mexico, Morocco, New Zealand, Norway, Peru, Philippines, Sweden, Taiwan, Thailand, and Turkey.

F. Conclusion

As the above analysis demonstrates, FDA finds that the estimated benefits exceed the estimated costs. The estimated costs are approximately one third of those in the PRIA, ranging from $677 million to $1.488 billion. These estimated costs were based primarily on the reports of some seafood firms and modeling done by FDA experts based on their experience with HACCP but also considered the study done under contract with NMFS. The benefits range from $1.435 billion to $2.561 billion and include benefits from safety, nutrition, increased consumer confidence, rent seeking activities, exports, and reduced enforcement costs.

G. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (Pub. L. 96–354) requires analyzing options for regulatory relief for small businesses. In the PRIA, FDA listed for comment a series of regulatory options on how to grant regulatory relief for small firms. In that document, FDA defined small firms as having less than $1 million in annual gross revenue (for non-shrimp processors) and less than $2 million for shrimp processors. In the PRIA, regulatory options for small business relief included:

(1) Requiring HACCP-type controls for those critical control points in individual plants that have a history of failure.

(2) Exempting very small processors from the requirements in the proposed regulatory option.

(3) Allowing a longer implementation period such that HACCP requirements may be phased in over a longer period of time.

(4) Providing generic HACCP plans (without mandatory control points) for certain types of operations, providing federal verification, or less frequent monitoring of critical control points.

FDA received a large number of comments on these options and on the costs that small businesses would incur as a result of the proposed option.

The agency has fully considered all of the comments received on its regulatory flexibility analysis and has responded to these comments in the full RIA. What follows is a summary of FDA's major conclusions from the analysis.

FDA received comments on whether there should be exemptions for processors based on either the size of the processor or the degree of risk associated with the product or process. For example, one commenter supported the exemption of small firms on the basis that small firms that represent 75 percent of the industry in terms of the number of plants, produce less than 10 percent of the seafood consumed.

FDA has concluded that there should be no exemptions for small firms. Small processors often engage in relatively high risk seafood processing, and an exemption based on size could inappropriately exempt high risk operations. An exemption based on risk might entail knowing which seafood might be responsible for a reported and confirmed illness. The agency finds however that because underreporting and skewed reporting of foodborne