estimate the time necessary for importers to develop a written verification plan, verify compliance of imports, and keep records of their verification activities.

Few comments provided information on the number of hours that a processor would expend on information collection and recordkeeping, as described in the preamble to the proposed regulation. One comment estimated that the annual burden would vary from 200 to over 700 hours, depending on the type of product, and another comment suggested that one hour per day, or 365 hours per year, would be required. One comment stated that the agency's estimate of 650 hours per year was reasonable. Another comment estimated four to five hours per day, or 1,820 hours per year as the likely burden. None of these comments provided information to support how the commenters arrived at their estimates.

It seems likely that the estimates suggested by the comments were calculated based on the same errors that the agency made in the proposal, that is, by combining the burdens associated with HACCP data collection and recordkeeping with other HACCP activities unrelated to information collection and recordkeeping, with usual and customary information collection and recordkeeping practices, and with collections of information required by the provisions of the Federal Food, Drug, and Cosmetic Act and implementing regulations. This conclusion is supported by the fact that some of the comments expressed agreement with the agency's calculations. For these reasons, FDA concludes that no changes in its corrected calculations are necessary to respond to the comments.

IV. Economic Impact

A. Introduction

In accordance with Executive Order 12866 and the Regulatory Flexibility Act, FDA has examined the impacts of the final rule. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act (Pub. L. 96–354) requires analyzing options for regulatory relief for small businesses.

The Unfunded Mandates Reform Act (Pub. L. 104–4) requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation). The Unfunded Mandates Reform Act also requires (in section 205) that the agency identify and consider a reasonable number of regulatory alternatives and, from these alternatives, select the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule. Even though FDA finds that the costs of this final rule may be below $100 million a year, estimating these costs is a difficult task involving uncertainties. This analysis, together with the preamble published in the Federal Register and supporting analysis and materials, constitutes a final RIA. Therefore, FDA has treated the final rule as an economically significant regulatory action under Executive Order 12866. Consequently, the agency has completed this full RIA which demonstrates that this rule is consistent with the principles set forth in the Executive Order and in these two statutes. In addition, this document has been reviewed by the Office of Management and Budget as an economically significant regulatory action under Executive Order 12866. FDA has concluded that the net benefits of this rule (benefits minus costs) are largest for the regulatory option selected as specified by Executive Order 12866. FDA has also concluded that, pursuant to the Unfunded Mandates Act, the regulatory option selected is the least burdensome option to accomplish the goal of controlling all physical, chemical, and microbiological hazards reasonably likely to be present in seafood.

As a part of the preamble to the proposed regulation, FDA published a summary of the Preliminary Regulatory Impact Analysis (PRIA) and placed on file with FDA's Docket Managements Branch the complete PRIA. In addition, FDA has placed the full final Regulatory Impact analysis on file at Dockets Management Branch (address above).

FDA has fully reviewed the information on which the PRIA was based, the comments on the PRIA, and other available information on the costs and benefits of HACCP for the seafood industry. Based on this review, FDA has arrived at two estimates of the costs in this final rule as well as upper and lower estimates of benefits. As can be seen in the agency's summary of costs and benefits are summarized in Table 2, FDA believes that the costs of the final rule will range from $677 million to $1.488 while the benefits will range from $1.435 to $2.561 billion. In its final analysis, the agency maintains that the total benefits of this mandatory seafood HACCP rule will exceed the total costs.

Regulatory Options

The agency raised and received comment on a number of regulatory options in the PRIA. The most significant two options raised were regulating only high risk products or the most serious hazards and providing regulatory relief for small businesses. The first option is inconsistent with the objective of this regulation, to control all physical, chemical or microbiological hazards reasonably likely to be found in seafood products. Although FDA has not granted relief only for small business, the agency has extended the compliance date for all firms from 1 year to 2 years.

TABLE 2.—SUMMARY OF TOTAL COSTS AND BENEFITS

Year	Costs from FDA models (millions)	Costs adjusted from NMFS model (millions)	Benefits lower (millions)	Benefits upper (millions)
1	$69	$162	$73	$108
2	42	9173	108	
3	41	83	85	156
4	38	80	87	158
Total[1]	677	1,482	1,435	2,561

[1]The total defines the total discounted costs and benefits beyond the 4th year and discounted at 6 percent.