I. Background

A. The Proposal

In the Federal Register of January 28, 1994 (59 FR 4142), FDA published a proposed rule to establish requirements relating to the processing and importing of seafood for commercial distribution in the United States. The requirements involved the application of HACCP principles by processors and importers to ensure food safety to the maximum extent practicable. HACCP is a system by which food processors evaluate the kinds of hazards that could affect their products, institute controls to keep these hazards from occurring or to significantly minimize their occurrence, monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

In addition to publishing the proposed rule, FDA published in the Federal Register of April 7, 1994 (59 FR 16655), a notice of availability of draft guidelines, primarily directed toward processors, on how to develop HACCP controls for specific types of processing operations. The notice of availability requested comments on the draft. Among other things, these draft guidelines, which were titled the ''Fish and Fishery Products Hazards and Controls Guide'' (the Guide), inventoried known likely food safety hazards associated with many species of seafood and many processing methods and made recommendations on ways to control those hazards. Comments received by FDA on the draft Guide are under review. The agency intends to publish the first edition of the Guide before the effective date of these regulations.

FDA established on the proposed rule a comment period of 90 days, to end on April 28, 1994. The agency also asked for comment on the draft guidelines by the same date. During that comment period, FDA held public meetings in nine cities to help ensure that the public was aware of the proposal, to answer questions about its contents, and to encourage participation in the rulemaking process through the submission of comments. In addition, at these meetings, FDA staff explained to the public how to use the draft guidelines to develop HACCP controls in specific processing operations.

The agency received several written requests for an extension of the comment period. After considering these requests, FDA published a notice in the Federal Register on April 7, 1994 (59 FR 16578), announcing a 30-day extension of the comment period to May 31, 1994, for both the proposed rule and the draft guidelines.

B. Factual Basis for the Proposal—Summary

In the preamble to the proposed rule, FDA stated five principal reasons for this initiative: (1) To create a more effective and efficient system for ensuring the safety of seafood than currently exists; (2) to enhance consumer confidence; (3) to take advantage of the developmental work on the application of HACCP-type preventive controls for seafood that had already been undertaken by industry, academia, some States, and the Federal government; (4) to respond to requests by seafood industry representatives that the Federal government institute a mandatory, HACCP-type inspection system for their products; and (5) to provide U.S. seafood with continued access to world markets, where HACCP-type controls are increasingly becoming the norm.

The preamble to the proposal cited the conclusion of a 1991 study on seafood safety by the National Academy of Sciences' (NAS) Institute of Medicine that, while most seafoods on the market are unlikely to cause illness to the consumer, there are significant areas of risk and illnesses that do occur. The study concluded that improvements in the current system of regulatory control are needed and repeatedly recommended the application of HACCP controls where warranted.

Ensuring the safety of seafood presents special challenges to both the industry and the regulator. Seafood consists of hundreds of edible species from around the world. Depending upon species and habitat, seafood can be subject to a wide range of hazards before harvest, including bacteria and viruses, toxic chemicals, natural toxins, and parasites. The harvesting of previously underutilized species—a practice that is increasing because of the depletion of traditionally harvested species—can be expected to create new source and process hazards that must be identified and controlled.

Unlike beef and poultry, seafood is still predominately a wild-caught flesh food that frequently must be harvested under difficult conditions and at varying distances from processing, transport, and retail facilities. It is also subject to significant recreational harvest, some of which finds its way into commercial channels. As fish farming (aquaculture) increases, new problems emerge as a result of habitat, husbandry, and drug use.

An additional complicating factor in ensuring the safety of seafood is the fact that no other flesh food is imported in the quantity, or from as many countries, as seafood. Over 55 percent of seafood consumed in this country is imported from approximately 135 countries. Several of these countries have advanced regulatory structures for seafood safety, but many others are developing nations that lack infrastructures capable of supporting national programs for seafood regulations comparable to those in more developed nations.

To ensure safety, it is of utmost importance that those who handle and process seafood commercially understand the hazards associated with this type of food, know which hazards are associated with the types of products with which they are involved, and keep these hazards from occurring through a routine system of preventive controls. For the most part, however, seafood processors and importers are not required, through licensure or examination, to demonstrate an understanding of seafood hazards as a prerequisite to being able to do business. In fact, there is evidence that such an understanding does not exist in a significant portion of the industry. A survey conducted by FDA from 1992 to 1993 of manufacturers of ready-to-eat seafood products revealed that, in significant measure, firms have not been employing the types of preventive processing controls necessary to ensure a safe product by design. FDA and State surveys have also revealed that many