of this section. These records are subject to the requirements of § 123.9.''

Additionally, FDA has moved the requirement that sanitation corrections be documented from proposed § 123.10 (d) to § 123.11 (b).

Finally, FDA notes that § 123.11 does not contain any mention of importers. The lack of a mention of importers in this section reflects the position that the agency is taking in these regulations that, to the extent that importers are also processors, they would be subject to the sanitation requirements in this section. To the extent that they serve as importers only, the sanitation provisions are not relevant to their operations.

L. Imports

1. Background

The majority of seafood consumed in the United States is imported. FDA's surveillance system for imports largely consists of reviewing the customs entries for fish and fishery products being offered for entry into the United States, engaging in wharf examinations and sample collections for laboratory analysis, and placing products with a history of problems on automatic detention. As with domestic inspections, this method is basically a ''snapshot'' approach that places a significant burden on the government to uncover problems. It has failed to result in full compliance or consumer confidence in the safety of imported seafood. Consequently, the agency tentatively concluded that HACCP controls should apply to imported fish and fishery products as well as to domestic products. Among other things, FDA proposed that the definition of ''processor'' explicitly include those who process seafood in foreign countries.

In addition, FDA tentatively concluded that the importer should share some responsibility with the foreign processor for safety. More often than not, it is an U.S. importer, rather than the foreign processor, who actually offers imported fish and fishery products for entry into the United States. The preamble noted that, while many importers are conscientious about the safety of the products that they import, others have little understanding of the potential hazards associated with their products. Thus, the agency tentatively concluded that the existing system of import controls had not promoted a sense of responsibility in the import industry.

Therefore, in addition to proposing to require that foreign processors that export to the United States comply with part 123, FDA proposed that importers of fish and fishery products take steps to ensure that their shipments are obtained from such processors. Specifically, FDA proposed that importers: (1) Have and implement a HACCP plan that describes how the product will be processed while under their control; (2) maintain a copy of the foreign processor's HACCP plan; and (3) take affirmative steps to ensure that the imported fish or fishery product was produced in conformance with the foreign processor's HACCP plan and with the proposed sanitation requirements. The agency also proposed that importers need not take affirmative steps if the fish or fishery product was imported from a country with which FDA has a MOU documenting the equivalency of the foreign inspection system with the U.S. system.

2. Should Imports Be Subject to These Regulations?

115. Approximately 70 comments addressed various aspects of the proposed requirements for imports. Approximately half of the comments that addressed the import provisions argued that it is necessary to subject imported products to the same regulatory requirements as domestically processed products. These comments were submitted by processors, trade associations, State and foreign government agencies, professional associations, and individuals. Many of these comments argued that exempting foreign processors from the requirements of these regulations would put the domestic industry at an unfair economic disadvantage. Other comments stated that the import requirements would increase consumer confidence in seafood because they would ensure that imported fishery products have been produced under the same HACCP requirements and held to the same sanitation standards as domestically produced product. A few comments suggested that imported products are more likely to present safety hazards than domestically-produced products because of a lack of understanding of CGMP's on the part of foreign processors. One comment asserted that a number of countries, including Canada, the EU, Iceland, and Thailand are in varying stages of establishing HACCP programs for their own domestic seafood processors.

Most of the remaining comments (approximately one-half) did not comment on whether HACCP controls should be required for imported fish and fishery products but discussed aspects of the agency's proposed approach. These comments will be addressed later in this section.

FDA did not receive any comments that persuaded it that imports should be exempt from the requirements of these regulations. On the contrary, the comments reflect a nearly universal recognition that the safety of seafood cannot be adequately ensured if the majority of products (that is, imports) are not subject to the same controls as domestic products.

Therefore, the agency has not modified the regulations' basic approach for imports.

116. Only two comments objected to the concept that imported fish or fishery products should meet the same requirements as those for domestic products. One of these comments argued that FDA should be tolerant of a foreign processor that may not have the knowledge or time to develop a HACCP plan before its product is ready for export and urged the agency to develop a temporary waiver system to accommodate such firms.

FDA is convinced that a 2-year implementation period, as discussed in the ''Effective Date and Compliance'' section of this preamble, will provide sufficient time for processors, both within and outside the United States, to develop and implement HACCP plans and otherwise come into compliance with the provisions of these regulations. The comment provided no basis for treating foreign processors any differently than domestic processors in this regard.

117. Another comment suggested that raw material fish and fishery products imported for further processing in the United States should be exempt from the requirements of the regulations but provided no reason to support that position.

The exemption requested by the comment would make it difficult, if not impossible, to control environmental hazards that may be associated with these products. This preamble and the preamble to the proposed regulations fully discuss the conclusions of the NAS, which identified raw material hazards, such as microbiological contamination in molluscan shellfish and natural toxins in both shellfish and finfish, as among the most pressing problems that must be addressed to ensure seafood safety. For the most part, these hazards are best addressed at the time of harvest and by primary processors, through HACCP, at the time of receipt. In many cases, there is little opportunity for control beyond the latter point. Raw material fish and fishery products for further processing comprise a substantial portion of fish