suggested by a comment, has used terminology consistent with the rest of the regulation in § 123.12(d). While proposed § 123.12 (a)(1) through (a)(5), which described the types of evidence that could be used to demonstrate compliance with the proposed regulations, reflected important principles for the importation of fish, based on the comments, FDA finds that these provisions were causing confusion, and that the statute can appropriately be implemented without including them in the final rule. For this reason, FDA has not adopted these provisions.

135. One comment asked what documents, if any, would have to be presented to FDA at the time of entry concerning the status of the foreign processor. Another comment suggested that importers should note on the entry documents that a HACCP plan is available for the foreign processor. This comment stated that FDA would have an opportunity to review the plan as part of its determination of whether to allow entry of the product.

FDA is not requiring that evidence of the importers' affirmative steps be presented along with the existing U.S. Customs Service entry documents as a matter of routine practice. It is possible that, in some circumstances, such a step will be necessary (e.g., where the agency has reason to believe that inappropriate conditions exist in the foreign processing facility). However, typically, the importer will be able to retain such evidence in its files and to make it available to the agency when FDA performs an inspection at the importer's place of business. Such a system is necessary because of the time that is necessary for the agency to properly review the importer's documentation of its affirmative steps and of the foreign processors' HACCP plans. Nonetheless, the agency is willing to explore alternate methods of implementing the import requirements of these regulations, such as that suggested by the comment. FDA welcomes a continuing public dialog about this matter.

136. One comment asked whether FDA would maintain an approved list of foreign processors.

The agency has no plans to maintain such a list, nor is it apparent upon what basis such a list would be prepared. A possible exception would be as part of an MOU arrangement, where the foreign country would agree to provide a list of ''approved'' firms to FDA. In such a situation, FDA would use reasonable means to inform the import industry of the purpose and contents of the list and update them as rapidly as possible when changes are made.

137. One comment expressed concern that the same foreign processor HACCP plan might be reviewed by different FDA investigators in different ports of entry, and that these investigators might reach different conclusions as to its adequacy. The comment urged that the agency coordinate such reviews, as well as reviews of importers' affirmative steps, in a way that would minimize inconsistencies.

FDA acknowledges that the situation might well arise where different investigators review the same foreign processor HACCP plan as a part of different importer inspections. To minimize inconsistencies in such reviews, the agency intends to train its inspectional staff in the requirements of these regulations and the application of HACCP principles to seafood processing, including training on the Guide. The agency also intends to develop guidance relative to importer verification activities.

M. Guidelines or Regulations?

1. Background

FDA recognizes that many processors will need guidance in the preparation of HACCP plans, and that HACCP plans will vary in complexity. The agency is committed to providing the industry with technical assistance that includes general guidelines for HACCP plans and the contents of plans for specific types of products and processes.

As part of FDA's seafood HACCP proposal, the agency included guidelines, in the form of appendices, on how processors of cooked, ready-to-eat products and products involving scombrotoxin-forming species could meet various provisions of the proposed regulations relating to the development and implementation of HACCP plans. FDA regards these products as being high-risk relative to other seafoods. They involve special considerations or special hazards for which additional guidance would likely be useful.

Cooked, ready-to-eat fishery products present an elevated risk of a microbiological hazard compared to most other seafood products. They are cooked as part of processing and might not receive additional cooking by consumers before consumption. Consequently, to be safe, these products must not contain pathogens at a level that will cause disease and must not be subjected to time-temperature abuse that would allow any existing pathogens to grow to unacceptable levels.

Scombrotoxin-forming species are fish that can form a toxin if exposed after death for significant periods to temperatures that permit the growth of certain bacteria. Scombrotoxin can result in a mild to severe allergic response in humans.

The guidelines for these products contained advice about hazards that are reasonably likely to occur and on details for HACCP plans for the control of these hazards. In addition to asking for comments on the substance of the guidelines, the agency asked for comment on whether these guidelines should remain as guidelines, or whether some or all of them should be adopted as regulations. As regulations, they would, essentially, tell processors that certain hazards must be controlled in their HACCP plans, identify in advance critical points in the processing of these products that processors must control to minimize these hazards, and tell processors what they would have to do, at a minimum, to maintain proper control of those critical points.

In another appendix to the proposed regulations, FDA published excerpts from the draft Guide, mentioned earlier in this preamble, for the stated purposes of publicizing the existence of that draft Guide and of providing processors with information about the types of guidance that the agency expected would be available in it.

One of the excerpts that FDA published was guidance on the processing of smoked and smoke-flavored fish. These products represent a significant hazard relative to contamination with *C. botulinum*, especially when packaged in reduced oxygen atmosphere packaging. FDA requested comment on whether this guidance should remain solely within the Guide, whether it should be provided an appendix to the regulations, or whether it should be adopted as regulations. The effect of adopting these materials as regulations would be the same as for the appendices described above.

If these materials remained in the form of guidelines, processors would be free to adopt them or not, so long as measures that provide an equivalent or superior degree of safety are implemented.

138. Approximately 55 comments responded to FDA's request for comment on whether these materials should remain as guidelines or be adopted as regulations. The majority of comments preferred guidelines. A few comments suggested that FDA initially issue guidelines, then possibly convert them to regulations after gaining experience with them as adjuncts to a functioning HACCP system or after pilot testing them. A few comments preferred to retain some of the materials as