provide adequate assurance that a given shipment of imported product was processed in compliance with that HACCP plan or that the sanitation requirements of § 123.11 were met. One additional thing is needed to provide such assurance: a written guarantee from the foreign processor that the products shipped to the importer are processed in accordance with these regulations. The guarantee is necessary to demonstrate that the HACCP and sanitation control systems are being implemented for products shipped to the importer. An importer should be able to make a reasonable judgement about the validity of the guarantee through a rudimentary review of the plan, as described below. Therefore, FDA is including these requirements in § 123.12(a)(2)(ii)(D).

FDA is also providing in § 123.12(a)(2)(ii)(D) that the foreign processors' HACCP plans that are maintained by importers be written in English, so that they will be meaningful to the importer and will allow for regulatory review.

128. As stated above, one comment cautioned the agency about the ability of many importers to evaluate the adequacy of HACCP plans that they might retain.

FDA acknowledges that many importers may not have the technical expertise to evaluate the adequacy of seafood HACCP plans. However, the agency is convinced that, as a result of the importers' assessment of the food safety hazards that are reasonably likely to be presented by the product, the importer should have developed some general expectations about the content of the HACCP plan (e.g., which hazards should be addressed). The importer should be able to spot any obvious shortcomings and to discuss them with the foreign processor. It is not enough that importers simply file away the documents upon receipt. Importers may find it advantageous to make a judgment about the likelihood that their product specifications will be met and to insist that they be given a guarantee that contains assurances that the specifications will be met.

129. Regarding the comment that complained about the potential loss of confidentiality of foreign processor HACCP plans that are provided to importers, since the agency has eliminated the requirement that all importers retain copies of foreign processor plans, the significance of this issue has been minimized. In the case where a foreign processor does not wish to share its plan with the importer, the processor and the importer would need to agree upon another means of providing for importer verification.

130. Regarding the comment that suggested that all foreign processors file their plans with FDA, the resource demands on the agency that would come with such an undertaking would be prohibitive. FDA cannot accept this suggestion.

8. Other Affirmative Steps

As a related matter, FDA has determined that, in the absence of a requirement that importers maintain a copy of the foreign processor's HACCP plan, finished product tests alone are insufficient as an importer affirmative step to ensure that the foreign processor is operating in accordance with these regulations. Finished product testing alone has a small statistical likelihood of detecting defects in a product, especially when the occurrence of such a defect is an uncommon event, as is the case with most seafood hazards (Ref. 213). The proposed requirement for the importer to obtain a copy of the foreign processor's HACCP plan, in addition to performing finished product testing, would have provided indirect evidence that HACCP controls are in place and would have lent support to a conclusion, based upon the analytical findings, that the relevant hazards are under control. In the absence of such evidence, the importer cannot reasonably conclude that the hazards are being controlled based solely on a negative analytical finding. For this reason FDA has required in § 123.12(a)(2)(ii)(E) that such sampling be accompanied by a written guarantee from the foreign processor that products being shipped to the importer are processed in a manner consistent with the requirements of these regulations. The guarantee provides the importer with reasonable assurance that HACCP and sanitation controls are in place and are being implemented, in a manner similar to the way that the foreign processor's HACCP plan would have under the requirements of the proposed regulations. Under this alternative, the importer would not have to maintain a copy of the HACCP plan.

For clarification and consistency within the document, FDA has revised the language of two of the affirmative steps to include reference to the sanitation provisions of the regulations. In both the proposed regulations and these final regulations the stated purpose of the affirmative steps is to enable the importer to verify that the fish or fishery product was processed under conditions that meet both the HACCP and sanitation requirements of these regulations. However, the formulations of two of the affirmative steps in the proposal did not make specific reference to sanitation. To avoid confusion over what the affirmative steps should cover, § 123.12(a)(2)(ii)(A) now reads ''Obtaining from the foreign processor the HACCP and sanitation monitoring records * * *'' and § 123.12(a)(2)(ii)(B) reads ''* * * certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part.''

131. Several comments asked the agency to specify the frequency with which the importer affirmative steps must be taken. A few comments suggested that the frequency should be no greater than the frequency of equivalent FDA verification activities.

It would not be practical for the agency to specify frequencies for affirmative steps that would be appropriate in all circumstances. Consistent with the frequency of monitoring by processors, importers should take affirmative steps to monitor their suppliers with sufficient frequency to accomplish its purpose—that is, to provide the importer with reasonable assurance that the foreign processor is operating in compliance with these regulations.

It would be inappropriate to tie importer affirmative step frequencies to average FDA sampling and inspection frequencies. FDA sample collection and inspection frequencies are determined, in part, by the compliance history of individual firms, agency priorities, and overall agency resources, not simply on a desired average minimum rate of verification. Thus, FDA's rate of inspection has no bearing on how frequently an importer should monitor a supplier.

132. A number of comments urged that the agency permit importers to contract with third parties to perform verification activities on their behalf. Two comments opposed such a provision but did not provide reasons for their position.

Several comments urged that certificates by nongovernmental third parties be accepted as an affirmative step. One of these comments, from a trade association, suggested that an equivalent arrangement has been accepted by FDA in controlling the importation of canned mushrooms from the Peoples Republic of China. This same comment argued that a system where individual importers inspect each of their suppliers is highly inefficient. The comment suggested that a single, technically competent party should perform the inspections. The trade association offered to serve as a