clearinghouse for the reports of such inspections. Likewise, the association offered to serve as a clearinghouse for finished product sample results for imported products, reducing the number of samples needed when the same product is imported by a number of importers. The comment further suggested that the association be permitted to hold foreign processor HACCP plans for its members, and perhaps for nonmembers. The comment argued that acceptance of this suggestion would reduce the number of duplicate records for the same product stored by various importers.

The agency accepts that third party verification can be an appropriate and efficient control mechanism. Such a system is consistent with the use of third parties by processors for plan development, record review, and CL deviation evaluation. Therefore, FDA has added a new provision at § 123.12(b), that reads, ''An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.'' It is worth pointing out that where an importer uses the services of a third party, the importer remains responsible for the verification procedures that are performed. The importers must be able to demonstrate that appropriate verification measures have been performed. This step may involve providing an FDA investigator with a copy of the foreign processor's HACCP plan, results of end-product sampling, results of an onsite inspection, the foreign processor's monitoring records, or the foreign processor's written guarantee. Third parties must, of course, be competent to perform the duties in question, and FDA reserves the right to challenge such competency. The agency has no objection to the use of clearinghouses for importer verification activities, as long as the forgoing requirements are met.

9. Importer Records

As previously mentioned, the proposed regulations would have required that importers develop and implement a HACCP plan. One effect of such a requirement would have been that importers would have had to maintain appropriate records. As has been explained, FDA is adopting only those essential components of the proposed approach that the agency considers to be practicable for importers. One such component is recordkeeping. Recordkeeping is essential in documenting for the benefit of importers and the agency the affirmative steps of importers, in the same way that it is essential in documenting the monitoring, corrective action, and verification activities of processors. For this reason, the agency has retained the recordkeeping aspect of the proposal for importers, in a manner that is consistent with the overall approach for importers in these final regulations. Section 123.12(c), which treats importer records identically to processor records, reads, ''The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 123.9.''

133. FDA proposed that importers encourage foreign processors to obtain HACCP training. A few comments urged the agency to make it clear that foreign processors must comply with the same training requirements as are applicable to domestic processors. One comment urged the agency to permit HACCP-training courses for foreign processors to be conducted in the country of origin by ''an official agency.''

FDA agrees that the need for training is the same for foreign processors as it is for domestic processors. The intended benefits of the training requirements are fully discussed in the ''Training'' section of this preamble. Nonetheless, the agency finds that the proposed requirement that importers encourage foreign processors to obtain training is unnecessary. Foreign processors that ship seafood products to the United States are advised of the training requirement of these regulations in the same way that they are advised of the other requirements of these regulations, through publication of the regulations. In addition, as mentioned elsewhere in this preamble, FDA intends to provide the embassies of seafood exporting countries with information concerning these regulations in order that they may in turn provide it to the processors in their countries. Consequently, FDA is not adopting this provision.

FDA has no objection to HACCP training being performed in the country of origin by ''an official agency'' or other entity, as long as the course of instruction is at least equivalent to that provided by the standardized course under development by the Alliance.

10. Determination of Compliance

FDA proposed to require that there be evidence that imported fish and fishery products were processed under conditions that comply with the requirements of these regulations, and that if assurances that this was the case did not exist, the product would appear to be adulterated and would be denied entry. This section of the proposed regulations provided five types of evidence that the agency would consider as adequate to provide such assurance.

134. A few comments supported these provisions. However, a few comments suggested that, if the importer is unable to provide assurance that a HACCP system is in place, the importer should be permitted to conduct finished product testing rather than having the product denied entry. One comment urged that importers be held only to a ''best efforts'' standard in determining whether their suppliers are in compliance with these regulations. This comment suggested that if an importer cannot determine that such compliance exists after using its best efforts, the importer's product should not be banned from the United States.

The purpose of these regulations is to cause processors of fish and fishery products, both domestic and foreign, to develop and implement HACCP systems of preventive controls to ensure the safety of their products. The importer requirements are designed to impose an obligation on importers to ensure that, like domestic products, the products that they are importing are not adulterated within the meaning of section 402(a)(4) of the act. This requirement means that importers must be able to satisfy themselves, and ultimately FDA, that the fish and fishery products that they are offering for import were produced subject to a HACCP system and sanitation controls designed to prevent insanitary processing conditions that may render the food injurious to health. If an importer does not have evidence that shows that the products were produced subject to such controls, it should not offer the product for import into this country. The lack of such evidence creates the appearance of adulteration that cannot be overcome by the collection and analysis of a finished product sample by an importer. Given the problems that can arise in seafood processing if HACCP and sanitation controls are not in place, under sections 402(a)(4), 701(a), and 801(a) of the act, FDA is adopting § 123.12(d), which provides that if evidence does not exist that an imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors, the product will appear to be adulterated.

Section 123.12(d) derives from proposed § 123.12 (a) and (b). FDA has combined these provisions and, as