sufficient control over the fish and fishery products that they offer for entry into their country to ensure that the products are produced pursuant to the requirements of these regulations. The agency recognizes that any one of the affirmative steps may not be appropriate or feasible for a particular importer or foreign processor. The regulations allow importers to select an affirmative step that is workable for their circumstances and to develop appropriate affirmative steps other than those listed in the regulations (see § 123.12(a)(2)(ii)(F)). However, such measures must provide at least an equivalent level of assurance of foreign processor compliance as that provided by the listed affirmative steps.

Additionally, FDA has modified the importer requirements to allow for the performance of any of the affirmative steps by a competent third party (§ 123.12(b)). This provision provides even greater flexibility to importers in meeting the requirements of these regulations.

Thus, FDA is not persuaded that the affirmative steps are not feasible or appropriate and has included them in these final regulations.

124. A comment argued that government certificates should not be acceptable unless they are issued by countries with which FDA has signed an MOU or similar agreement. The comment asserted that, especially in developing countries, there may be different interpretations of the regulations, and differences in competency, credibility, infrastructure, intent, and uniformity that might bring the utility of such certificates into question.

FDA acknowledges that it is likely to have a higher level of confidence in certificates received from a government entity with which it has signed an agreement than with one with which no agreement exists. However, as discussed above, it is unlikely that the agency will be able to negotiate an MOU with every country that exports seafood to the United States. Thus, there may be countries that have excellent certification programs with which FDA, for a variety of reasons, simply does not have an opportunity to enter into an agreement. Moreover, if the agency learns, either through its own routine surveillance activities, consumer complaints, or other means, that there is evidence that a country is routinely issuing certificates inappropriately, the agency will try to inform firms that import fish or fishery products from that country that it will expect them to use other means of verification if they want to avoid the appearance that those products are adulterated under section 402(a)(4) of the act (see § 123.12(d)).

125. One comment urged that certification be permitted on a continuing basis rather than requiring lot-by-lot certification.

FDA agrees that continuing certification is appropriate and notes that the language and intent of the proposed regulations would have allowed for it. Nonetheless, in an effort to further clarify this situation, the agency provided in § 123.12(a)(2)(ii)(B) that: ''Obtaining either a continuing or lot-by-lot certificate * * *'' will be one way to satisfy the requirement that an importer take affirmative steps to ensure that the product is produced in accordance with the requirements of this part.

7. Foreign Processor HACCP Plans

126. Approximately 15 comments addressed whether importers should be required to have on file copies of the HACCP plans of each of their foreign processors. Approximately half of these comments supported such a requirement, although for the most part they provided no reasons for their support. The other half objected to the requirement. One of these comments argued that possession of a foreign processor's HACCP plan would be cumbersome for the importer and would provide no assurance that product shipped by that processor was processed in accordance with the plan. One comment cautioned that it would be unrealistic to expect that importers could make any but a rudimentary judgment as to the adequacy of foreign processors' HACCP plans. Such judgments, these comments asserted, should be reserved for the regulator when the plans are assessed during inspections of importers' records.

One comment cited the possibility of breaches in confidentiality because commercially sensitive material would be supplied to importers. A related comment suggested that, to solve the confidentiality problem, the foreign processors' HACCP plans should be filed directly with FDA rather than with importers.

Although the agency continues to believe that a foreign processor's HACCP plan provides a useful basis for verification, FDA is persuaded by the comments that there are logistical and other issues that could render the retention of HACCP plans by importers unmanageable in some cases. FDA has also concluded that, in most cases, affirmative steps such as those listed in § 123.12(a)(2)(ii) (e.g., onsite inspection by the importer and certification by a foreign government agency) will be adequate to enable an importer to verify that the products being imported are safe in accordance with the requirements of these regulations.

As described previously, the NACMCF recommendations describe two primary goals of verification: (1) Ensure that the plan is adequate to address the hazards that are likely to affect the product; and (2) ensure that the plan is being consistently implemented. The affirmative steps listed in § 123.12(a)(2)(ii) are designed to address both of these functions. For example, obtaining HACCP and sanitation monitoring records from the foreign processor (§ 123.12(a)(2)(ii)(A)) enables the importer to confirm that the foreign processor has addressed the relevant hazards and sanitation concerns (i.e., those for which there are monitoring records), and that it is monitoring to ensure that these concerns are under control during the production of lots that are shipped to the importer. Similarly, obtaining governmental or third party certification of foreign processor compliance with the requirements of these regulations (§ 123.12(a)(2)(ii)(B)) or inspecting the foreign processor directly (§ 123.12(a)(2)(ii)(C)) enables the importer to confirm that the foreign processor has an adequate HACCP plan and SSOP, and that the relevant sanitation and safety concerns are being controlled for those lots that are shipped to the importer. The affirmative step options provided for by § 123.12(a)(2)(ii)(D) and (a)(2)(ii)(E) are discussed later in this section.

Consequently, FDA has not included a requirement that importers of fish and fishery products have on file the HACCP plans of each of their foreign suppliers in these final regulations.

Nonetheless, FDA points out that maintaining copies of these plans could be one of several measures that an importer could incorporate into its affirmative steps. Therefore, these final regulations in § 123.12(a)(2)(ii)(D) incorporate the concept as one of the affirmative steps that an importer may choose to use for verification purposes.

127. One comment noted that the plans of foreign processors would normally be prepared in the native language of the country of origin and asked whether FDA would require that these documents be translated into English. On the other hand, another comment recommended that HACCP plans be maintained in both the language of the native country and in English.

FDA agrees with the comment that argued that a copy of a processor's HACCP plan would not, by itself,