the food that it is offering for import into the United States is not adulterated under section 402 of the act, including section 402(a)(4), one of the principal provisions on which these regulations are based.

Currently, however, the importer is not required to operate in a proactive manner to ensure that it is meeting this responsibility. Rather, the importer need only offer products for entry into commerce and thereby place the burden on the government to find a problem. Many importers traditionally have purchased ''FDA rejection insurance'' to hedge against that possibility. The government can shift the burden to the importer by placing the importer's products on automatic detention if it finds problems that warrant such a step, but in most instances the burden remains on the government.

Second, responsible importers understand the issues related to the safety of the seafood products that they import and customarily require that foreign suppliers conform to their product specifications and applicable U.S. regulations relating to safety. These importers take various measures to ensure that a foreign processor can comply with their specifications and safety requirements before they agree to purchase products from the foreign processor.

Thus, it is feasible for importers to take steps to ensure that they are not offering adulterated products for entry into U.S. commerce. Requiring such measures will not be a significant added burden for many importers, particularly as HACCP principles become more widely used and understood in international commerce. Foreign processors that want to participate in the export market, not only to the United States but to the EU, Canada, and an increasing number of other countries, will implement HACCP and sanitation control programs and will be prepared to address an importer's needs for verification.

FDA does not agree that there is no parallel in the domestic scheme to the importer's responsibility to ensure that the goods it is offering were produced under HACCP. Domestic processors, like importers must work with their suppliers (e.g., fishermen) to ensure that all reasonably likely hazards (e.g. natural toxins and agricultural and industrial chemical contaminants) are controlled. FDA is confident that importers, like processors, will realize that ensuring that foreign processors institute preventive control systems is a cost effective means of ensuring that the products that they offer for entry into the United States will consistently meet FDA's entry requirements and will be safe for consumption. FDA also disagrees with those comments that suggested that a requirement that importers take steps to ensure that the products they offer for entry have been produced under a HACCP plan is an abrogation of FDA's responsibilities. As stated previously, the industry has a responsibility to ensure that the food that it introduces into interstate commerce is not adulterated. FDA has a responsibility to verify that industry is meeting its obligation and to take remedial action if industry fails to do so. Importers, who are usually the owners of the products that they are offering into commerce, are a part of that industry. FDA cannot accept that importers have no responsibility to ensure that their products are not adulterated.

The agency recognizes that probably the most effective way for a regulatory agency to evaluate a processor's compliance with the HACCP and sanitation requirements is through onsite inspection of facilities, practices, and records. FDA has performed a limited number of inspections of foreign processors and, within its budgetary limitations, will continue to do so to enforce these regulations. However, such inspections are costly, and any attempt to significantly increase their number would require additional resources.

FDA will continue its traditional import surveillance role, utilizing entry document review, wharf examinations, sample collections, and automatic detentions as screening tools. These tools indirectly evaluate the adequacy of HACCP and sanitation controls and will continue to be useful in detecting significant problems. While end-product testing and evaluation are not adequate substitutes for preventive controls in ensuring the safety of a product, they can provide verification where appropriate (Ref. 34, pp. 201–202).

FDA has concluded that requiring HACCP controls, together with import surveillance and periodic inspections of importers to ensure their compliance with the requirements of § 123.12, will better ensure the safety of imports than the current system.

In a related matter, § 123.3(g) makes clear that, under ordinary circumstances, freight forwarders, custom house brokers, carriers, or steamship representatives will not be required to fulfill the obligations of an importer. It is possible, although FDA has no way to know with any certainty, that some of those that objected to being required to fulfill those obligations would, as a result of these clarifications, find that they would not be expected to do so.

4. Memoranda of Understanding (MOU's)

120. Many of the comments that objected to the importer responsibility provisions of the proposal on the grounds that the government is the appropriate entity to ensure foreign processor compliance, stated that the most effective means of ensuring such compliance would be for FDA to enter into MOU's with the governments of exporting nations. Approximately one-third of those that commented in any way on the importer provisions urged FDA make the negotiation of MOU's a high priority. Only one comment objected to the development of MOU's.

Several comments argued that FDA should develop MOU's with all countries from which seafood is imported. One of these comments pointed out that to do otherwise would unfairly cause the obligations of importers to vary considerably. A few comments argued that the existence of an MOU should be a prerequisite for the importation of seafood products from a country. One of these comments stated that mandatory MOU's would reduce the complexity of the present import surveillance situation, reduce the number of countries exporting seafood to the United States, and encourage the development of improved food safety programs in exporting countries. Another comment asserted that MOU development is appropriate because government-to-government relationships and audits can be free of influence from packers and importers, whereas foreign suppliers may be prone to provide false assurances about their programs to prospective importers.

One comment urged FDA to fully describe the process and criteria for developing and evaluating MOU's and expressed concern about the process because of the varying level of sophistication of foreign seafood control programs. One comment stated that the foreign government should be responsible for evaluating the foreign processor's HACCP plan, inspecting the foreign processor, periodically analyzing products produced by the foreign processor, and issuing health certificates. A few comments stated that FDA should monitor the effectiveness of the foreign government's control program in a manner that is authorized in the MOU. These comments stated that, under the MOU's, the foreign government should provide FDA with periodic lists of processors that meet the requirements of these regulations, or, alternately, that all seafood processors