and fishery products imported into the United States (Ref. 212, p. 49). Thus, to exempt foreign processing of such products from the requirements of these regulations would be to greatly diminish the scope and, therefore, the overall effectiveness of these regulations.

118. One comment that supported the need for equitable treatment of imported and domestically produced products urged the agency to provide the same opportunities for processors abroad to familiarize themselves with the requirements of these regulations as it does the domestic industry. The comment argued that just printing the regulations in the Federal Register would not fulfill that responsibility. The comment further suggested that FDA send copies of guidance materials to all known foreign seafood processors, preferably in their native language.

FDA acknowledges the difficulty in reaching foreign processors with information about the requirements of these regulations. However, mass mailings to, and multiple translations of, these regulations and the Guide for all foreign seafood processors that export to the United States would not be practicable for FDA.

The agency intends to reach foreign processors primarily by briefing foreign embassy staffs and by communicating with U.S. importers during public and trade association meetings. Based on experience in disseminating information about U.S. requirements to the import community, the agency expects that these two groups will provide the necessary information and guidance materials (in the appropriate languages) to the foreign processors that they represent. This same approach was used in disseminating information about the proposed regulations. In fact, FDA became aware of a Japanese translation of the proposal shortly after it issued.

In addition, FDA traditionally has provided training and technical assistance for foreign processors and government officials on a variety of food control topics, within the constraints of budget and manpower. These projects have principally been conducted in developing countries, often those in which the agency has become aware of a particular problem that threatens the safety of products offered for entry into the United States. FDA anticipates that these kinds of projects will continue, and that they will focus more closely on HACCP. FDA also expects that HACCP training, performed in accordance with the standardized training materials under development by the Alliance (see the ''Training'' section of this preamble), will provide further opportunity for foreign processors to be exposed to the requirements of these regulations.

3. Should Importers Be Subject to These Regulations?

119. Approximately half of those who commented on the import provisions addressed whether the importer should be required to take steps to ensure that its shipment originates from a foreign processor that operates under HACCP. Approximately half of these comments favored the concept and half opposed it, with both groups being diverse in their representation.

Of those who opposed it, many argued that these requirements should be the responsibility of the government, and that FDA should not require that importers enforce them. A number of these comments further argued that equivalent foreign government inspection systems cannot be presumed to be in place, and that the only way to achieve a ''level playing field'' is for FDA to perform inspections of foreign processors at the same frequency, and using the same standards, that the agency applies to domestic processors. One comment suggested that it may be necessary to obtain legislative authority to perform foreign inspections, as a condition of importation. Another comment suggested that FDA auditing of foreign processor compliance would give importers assurance that the products that they obtain from such sources had been produced in accordance with appropriate U.S. standards.

One comment, while not opposed to mandatory importer responsibilities, nonetheless argued that FDA should spend as much time and effort inspecting foreign processors as it does on domestic processors because over 50 percent of the seafood consumed in the United States is imported. The comment continued that, ''to do any less would be an unfair burden to domestic processors and would not accomplish the stated goal to significantly improve the safety of seafood consumed in the U.S.''

One comment argued that there is no real cost savings in assigning importers the responsibility of verifying foreign processor compliance rather than assigning that responsibility to FDA, because importers will merely pass along the additional costs to the consumer. Another comment noted that many small importers obtain products from over 25 countries, and that they cannot afford to provide the surveillance necessary to ensure compliance.

Another comment argued that many importers function simply as brokers, connecting a buyer with a seller, and that they lack the expertise, manpower, and facilities to evaluate the adequacy of a processor's HACCP controls. One comment stated, ''Many of the people involved in importing never see the product and know nothing about fish—these are people in a small room with a battery of phones!'' Another comment argued against placing reliance for assuring the safety of imported seafood on persons who have a financial interest in the product but lack the required knowledge about seafood safety.

One comment argued that requiring importers to exercise control over their suppliers has no parallel in the proposed domestic HACCP scheme. The comment stated that domestic processors must control the hazards that are introduced during their processing operations but need not be involved in verifying the control of those hazards associated with their supplier's operations. Some comments argued that the responsibility for controlling hazards that are reasonably likely to occur should be assigned to the foreign processor, while others argued that it should be assigned to the U.S. processor to whom the importer sells the product. One comment asserted that importers are not in a position to exercise control over the processing of products in foreign plants any more than they are in a position to exercise control over how the products are handled by their customers.

Most of those comments that supported the concept of importer responsibility provided no reason. However, one comment stated that requirements on importers would ensure that someone in the United States would be legally responsible for the safety and wholesomeness of each imported product.

FDA recognizes that requiring importers to take steps to ensure that foreign processors from whom they purchase seafood products are in compliance with these regulations could necessitate significant changes in the operations of importers who have limited their activities to matching buyers with sellers based on product specifications that may have had little to do with safety. However, for two reasons, FDA cannot agree that responsibility with regard to safety is inappropriate for importers.

First, it has always been the importer's responsibility to offer for entry into this country products that are not adulterated under U.S. law. It is a prohibited act, under section 301(a) of the act, to introduce into interstate commerce an adulterated food. Thus, an importer would be committing a prohibited act if it failed to ensure that