which fish is a characterizing ingredient.'' This revision will serve to ensure that mandatory HACCP requirements do not apply to products that contain inconsequential amounts of fish from a public health standpoint.

31. One comment stated that fish oil that is intended for use in human food should not be subject to the requirements of these regulations until it has been separated, through initial processing, from the oil that will be used for animal feeds and other industrial purposes. FDA does not find that the comment provided sufficient justification to treat this product differently from other human food products processed from fish. The agency acknowledges that the hazards associated with these products may be minimal. If that is the case, the fish oil processor's burden will also be minimal, perhaps limited to training expenses and the performance of a hazard analysis. Moreover, these regulations do not apply to products that are not for human consumption and fish oil processors that are confident that their production will not be used for human consumption need not apply the requirements of these regulations.

7. Food Safety Hazard

32. A number of the comments recommended that FDA define ''safety hazard'' or ''food safety hazard.'' Several of these comments recommended that FDA adopt a definition that is consistent with the NACMCF recommended definition for ''hazard.'' The comments were primarily concerned with the coverage of these regulations. They urged that the regulations be clear that only food safety hazards need be addressed by the HACCP plan and argued that a definition would help to accomplish that.

The NACMCF definition of ''food safety hazard'' reads, ''A biological, chemical, or physical property that may cause a food to be unsafe for consumption.'' While FDA provided no definition of ''food safety hazard'' in the proposed regulations, it did raise the issue of the coverage of the regulations in proposed § 123.6(b) (redesignated as § 123.6(c)), which mandated coverage of food safety hazards only and listed nine types of food safety hazards posed by the various types of fish and fishery products. This list included examples of biological, chemical, and physical hazards. Additionally, the preamble to the proposed regulations discussed at length the significance of a number of these types of hazards.

FDA agrees that the meaning ascribed by the agency to a food safety hazard should be as clear as possible in these regulations. The examples of hazards in the proposed regulations—and codified in these final regulations—are consistent with the NACMCF definition for a food safety hazard. Therefore, for the sake of clarity, FDA has decided to characterize these examples in a definition § 123.3(f), which reads, ''*Food safety hazard* means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.'' The only difference between this definition and the NACMCF recommendation is the addition of the word ''human.'' FDA has included this word to prevent confusion about the application of these regulations to pet or animal feed.

In keeping with the new definition, and to provide further clarification about the nature of the hazards that are required to be addressed by these regulations, the term ''hazard'' has been changed to ''food safety hazard'' where it appears throughout the codified portion of this document.

8. Harvester

FDA proposed to define ''harvester'' as ''a person who has an identification number issued by a shellfish control authority for commercially taking molluscan shellfish by any means from a growing area.'' After review, the agency has concluded that it was not necessary to limit ''harvesters'' to those persons who have an identification number, primarily because in some jurisdictions, identification numbers may not be issued by a shellfish control authority. Without this limitation, FDA has concluded that there is no need to establish a particular meaning for this term for the purposes of these regulations. Therefore, the agency has removed this definition from the final regulations.

9. Importer

FDA proposed to define ''importer'' as ''a person, or his representative in the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.'' The preamble to the proposed regulations explained that the importer is the owner of the imported goods or the owner's representative in the United States. The preamble further noted that freight forwarders, food brokers, food jobbers, carriers, and steamship representatives would not usually be considered to be the importer of the product for the purposes of these regulations because they are not usually in a position to make decisions that can ensure the safety of the product. However, the preamble did not categorically rule out that these individuals could be the importer because sometimes they may be in a position to make decisions relevant to safety.

33. Several comments stated that FDA should modify the definition of ''importer'' to specifically exclude intermediary agents involved in the importing process, such as freight forwarders, licensed U.S. customs brokers, food brokers, food jobbers, carriers, and steamship representatives. These comments noted that, although imported products may enter the United States under the name of an intermediary, this practice is done for convenience in handling the paperwork at the port of entry. The comments stated that the intermediary has little responsibility for conducting the negotiations with an overseas producer and rarely takes possession of the products. Therefore, the comments stated, the intermediary has limited influence on the safety of the imported goods. Two comments pointed out, for example, that customs brokers that provide their clients with the service of using the broker's customs bond are listed as the ''importer of record'' and may thereby, unintentionally, be regarded as importers under the proposed definition, even though they do not own or control the product being imported.

Conversely, two comments argued that agents, such as food brokers, should be included in the definition of an ''importer'' because they bring product into the United States and sell it. The comments argued that the brokers should, therefore, be held responsible for ensuring that the foreign processor complies with the provisions of these regulations, to avoid an unfair advantage over domestic processors.

FDA concludes, based on the information provided in the comments, that these intermediaries can neither be categorically included or excluded. However, the agency recognizes that the number and type of comments on this issue demonstrate that the language of proposed § 123.3(h) was inadequate to convey the agency's intent, as articulated in the preamble. For this reason, FDA has clarified the definition of ''importer'' in § 123.3(g) to read, in part:

> *Importer* means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.