values within which the parameter must be controlled to protect against the occurrence of a food safety hazard.

For consistency with the definition of ''critical control point,'' FDA has added the phrase ''food safety'' before the word ''hazard'' in the text of § 123.3(c). The language in the final regulation now reads, ''*Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.''

5. Fish

26. FDA proposed to define ''fish'' as ''fresh or saltwater finfish, molluscan shellfish, crustaceans, and other forms of aquatic animal life other than birds or mammals.'' A significant number of comments suggested that FDA should modify this definition to clarify whether it includes species such as sea snails, abalone, frogs, alligators, turtles, other reptiles, amphibians, sea cucumbers, plants, or algae.

FDA agrees that this type of clarification would be helpful and has modified the definition at § 123.3(d) to read:

Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

The term ''mollusks'' includes abalone, sea snails, and land snails (e.g., escargot and any other terrestrial gastropods, such as the giant African land snail (*Achatina fulica*)). The addition of examples of aquatic animal life and the mention of mollusks are intended to make clear which species are covered by the term ''fish.'' Water-dwelling reptiles and amphibians other than alligators, turtles, and frogs have not been specifically listed because they are not significant commercial food sources in the United States. Finally, FDA notes that, consistent with the proposed definition, aquatic plants (including algae) are excluded. This definition is consistent with the traditional treatment of these products by FDA.

The new language also serves to emphasize that these regulations apply only to those products that are intended for human consumption. This point was explicit in the proposed definition for ''fishery product'' but was inadvertently not mentioned in the proposed definition of ''fish.''

27. Two comments contended that there should be separate definitions for finfish and shellfish, to differentiate between relative levels of safety concerns (e.g., high and low risk).

FDA disagrees with this comment. Such a differentiation would serve no purpose in these regulations. The purpose of these regulations is to set up a unitary system that responds to a particular product based on the risks it presents, not to establish a system that is divided up based on risk presented. The merits of differentiating between products on the basis of risk is addressed in the section of the preamble entitled ''Should Some Types of Processors be Exempt?''

6. Fishery Product

FDA proposed to define ''fishery product'' as ''any edible human food derived in whole or in part from fish, including fish that has been processed in any manner.'' The preamble to the proposed regulations stated that the intent of the definition was to include products that contain seafood as an ingredient as well as those products that are comprised of seafood alone, because hazards derived from seafood are reasonably likely to occur in both types of products.

28. A few comments urged that FDA exclude from the meaning of ''fishery product'' any product that is made in whole or in part from commercially sterilized fishery products subject to the requirements of parts 113 and 114, (i.e., thermally processed low-acid canned foods and acidified foods).

FDA disagrees with this comment. Although such foods are required to be produced in accordance with certain HACCP-type control procedures to reduce the risk of the hazard of *C. botulinum* toxin production, these control measures do not address other potential hazards. For example, part 113 provides no assurance that the raw material used in the canning of tuna will be free from contamination with dangerous levels of histamine. Likewise, products made in part from low-acid canned foods and acidified foods can also present hazards that must be addressed. For example, a salad made in part from canned tuna can be subjected to recontamination with pathogenic microorganisms and time-temperature abuse during preparation.

Although FDA cannot exclude those products made in whole or in part from low acid canned foods or from acidified foods from the definition of a ''fishery product,'' it is worth noting that the agency has exempted processors who are following the requirements of part 113 or part 114 from having to include controls for *C. botulinum* in their HACCP plans. This hazard is already addressed by the requirements in those parts (see § 123.6(e) of these regulations and the ''HACCP Plan'' section of this preamble).

29. One comment suggested that the language of the proposed definition inappropriately excludes fish roe.

FDA points out that the phrase ''any edible human food product derived in whole or in part from fish,'' in the proposal was intended to cover these products. FDA, however, has modified the definition of ''fishery product,'' and it no longer includes this language. Therefore, to make clear that roe are covered, FDA has made explicit in the definition of ''fish'' that the roe of the covered animals are included.

30. A significant number of comments urged that the definition exclude products that contain only a minimal amount of fish. These comments suggested various standards that FDA should apply to exclude such foods from the definition. These included: Products that contain less than 50 percent fish; products that contain less than 10 percent fish; products that contain 2 percent or less of cooked, or 3 percent or less of raw, fish; products in which fish is not a characterizing ingredient; and products that contain any nonfish ingredient unless a hazard analysis identifies a significant hazard associated with the fish ingredient. The comments provided no justification for the percentages suggested.

FDA agrees that foods that contain inconsequential amounts of fish, such as Worcestershire sauce, are not the types of foods that should come under the purview of these regulations. It is doubtful that they pose reasonably likely hazards associated with their fish components. Moreover, these products are neither represented nor perceived as being fish-based foods.

The comments provided FDA with no basis, however, upon which to select a specific minimum content of fish ingredient for the definition of ''fishery product.'' There is no obvious minimum percentage of fish on which to exempt a food that contains only a small amount of fish from the provisions of these regulations.

Instead, the agency accepts the comment that, to meet the definition of a ''fishery product,'' a food should be characterized by the qualities of the fish that it contains. Thus, these regulations will apply to those foods whose basic nature is defined by the fish that they contain. Accordingly FDA has modified the proposed definition (§ 123.3(e)) to read in part, ''*Fishery product* means any edible human food product in