the product from the fisherman or aquacultural producer. As such, they are often in the best position to control environmental hazards, as was previously discussed. They also often store the product, at least for short periods of time. In this capacity, they may be responsible for ensuring that the product is not exposed to time-temperature abuse, a phenomenon that critically affects the safety of some products.

For these reasons, FDA has clarified the definition of ''processing'' at proposed § 123.3(m) (redesignated as § 123.3(k)) to specifically include dockside unloading.

41. One comment took the view that only processors who own the products that they are processing should be subject to these regulations and suggested that the term ''processor-owner'' be substituted for ''processor.'' Several other comments questioned whether custom processors that do not own the product, should be subject to the provisions of these regulations.

The definition of ''processor'' does not hinge on ownership. As indicated earlier, whether a product is adulterated under section 402(a)(4) of the act depends on the condition under which it was ''prepared, packed, or held.'' Ownership is not a relevant factor. Consistent with this principle, these regulations define a processor as simply an entity that engages in processing. ''Processing'' is defined as including a number of activities, such as manufacturing and packing, that are normally performed by a custom packer.

Like warehouses that store products for distant owners, custom packers are often in the best position to exercise HACCP controls for the products that they process. Because of the real-time nature of HACCP (i.e., because monitoring provides immediate feedback as to whether a hazard is being controlled), the processor can most effectively apply HACCP monitoring controls to a food being processed, regardless of whether the processor is the actual owner of the food. FDA recognizes that it will often be beneficial for the custom processor and the owner of the product to fully discuss and agree upon the HACCP controls that will be effected by the custom processor while the product is in its possession.

42. One comment argued that custom packers should be included within the scope of these regulations because these processors often can or smoke recreationally caught products and are often the only commercial entity that can assure the safety of such products. While the definition of ''processing'' clearly covers the kinds of activities performed by custom packers, it is not the intent of these regulations to address arrangements between a recreational fisherman and a custom packer for the processing of fish for the personal use of the fisherman. The regulations only cover custom packing that is performed on behalf of an owner who intends to introduce the fish into interstate commerce. Nonetheless, the agency does not believe that clarification to the regulations is needed on this point.

43. One comment urged that aquacultural producers that also eviscerate the fish before delivery to a processing plant be required to comply with the requirements of these regulations.

FDA agrees with the comment and further states that the process of eviscerating is specifically included in the definition of ''processing.'' Eviscerating is excluded from the definition only when it occurs on a harvest vessel for the purpose of preparing the fish for holding en route to the processor.

44. A few comments objected to FDA including labeling in the definition of ''processing.'' The comments argued that labeling operations are unlikely to introduce hazards to the product. FDA has considered these comments but finds that there is potential during some labeling operations for the development of hazards. For example, improperly controlled labeling operations for scombroid species could result in time-temperature abuse of the product, increasing the risk of histamine contamination. Cooked, ready-to-eat products could similarly be subjected to time-temperature abuse, resulting in the potential for pathogen growth. The inclusion of labeling in the list of processing operations is not intended to imply that this step should always, or even frequently, be considered a CCP. That can only be determined through the conduct of a hazard analysis.

FDA proposed to exempt ''heading or gutting intended solely to prepare a fish for holding on board a harvest vessel'' from the definition of ''processing.'' In drafting the proposed regulations, FDA was concerned that, in the absence of such an exemption, harvest vessels that are presently heading or gutting fish would stop the practice to avoid being subject to the requirements of these regulations. FDA did not want an inadvertent consequence of these regulations to be a reduction in product quality. In addition, FDA tentatively concluded that safety hazards introduced by these operations are generally minimal.

45. One comment noted that FDA should include the practice of freezing fish on harvest vessels in the list of exempted operations.

FDA agrees that freezing is an operation that is routinely used onboard a harvest vessel in order to preserve the quality of the fish until it is landed for further processing (e.g., freezing performed onboard tuna harvesting vessels). For this reason, the agency has revised the definition of ''processing'' to include an exemption for onboard freezing.

46. One comment suggested that FDA also exempt onboard scallop shucking operations.

Unlike shucking other molluscan shellfish, shucking scallops involves eviscerating, a procedure that falls within the exemption in § 123.3(k). Consequently, onboard shucking of scallops does not constitute processing for purposes of these regulations. The agency does not believe that a change in the definition is necessary in this regard.

47. One comment suggested that, with respect to molluscan shellfish, ''processors'' should include shellfish shippers, reshippers, shucker-packers, repackers, and depurators.

The persons that perform all of these types of operations are ''processors'' under § 123.3(k)(1) and subject to the provisions of these regulations. Thus, the agency has concluded that no change in the definition is necessary.

16. Scombroid Toxin-Forming Species

The term ''scombroid toxin-forming species'' appears in § 123.6(c)(1)(vi) of this final rule. While FDA did not propose to define this term in the codified portion of the proposed regulations, it did propose to define it in part 123 appendix B as:

> [T]una, bluefish, mahi mahi, mackerel, sardines, herring, kahawai, anchovies, marlin, and other species, whether or not of the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

Appendix B of part 123 is no longer included in these regulations, as is discussed elsewhere in this preamble. Consequently, FDA is transferring the definition from part 123 appendix B to § 123.3(m) to clarify the meaning of § 123.6(c)(1)(vi).

48. A number of comments objected to the inclusion of herring in the list of scombroid toxin-forming species, arguing that there has been no association between herring and cases of histamine poisoning.

In response to the comments, FDA has modified the definition of scombroid