hazard analysis may reveal the need to control certain aspects of sanitation in the HACCP plan, especially to control hazards involving microbiological contamination. One comment noted that sanitation controls are likely to be components of the HACCP plans of molluscan shellfish processors.

Given the strong support that sanitation controls should be included in HACCP plans where they are critical to safety, FDA has no objection to processors including sanitation controls in their HACCP plans. Consequently, these final regulations state in § 123.6(f) and § 123.11(d) that sanitation controls for safety may be included in HACCP plans.

The agency has concerns, however, as to whether including sanitation controls in a HACCP plan will be adequate to ensure that appropriate conditions exist in a plant. The conditions that would be addressed in the HACCP plan will likely be those that are most critically and directly related to product safety. Other situations that are relevant to safety, but in a less direct way, would probably not be controlled through HACCP. For example, following the NACMCF recommendations for hazard analysis and HACCP plan development would likely result in the identification of a number of equipment and hand washing controls at CCP's in the HACCP plan for the processing of a cooked, ready-to-eat product to minimize the risk of microbiological contamination but not in the identification of these same controls in the HACCP plan for a raw finished product that would normally be cooked before consumption. In the latter case, however, attention to sanitation would still be important in the processing plant to prevent contamination of the product, given that the ultimate consumer cook may be inadequate, or that the product, once contaminated, could be a source of cross-contamination to other foods.

Likewise, the potential for contamination of either a cooked, ready-to-eat product or a raw product as a result of rodent activity in a processing plant, or as a result of improper use of pesticides on or near the product, would not likely be identified in a HACCP plan. All of these conditions are relevant to the safety of the product and should be addressed by processors. It is not clear whether HACCP can fully succeed in plants that are not in control of general sanitation practices. The inclusion of sanitation in HACCP—as desirable as it may be—will not fully resolve this problem.

b. *SSOP.*

111. As indicated above, a significant number of comments that addressed alternatives to the prescriptive approach to sanitation in the proposal preferred a SSOP, either alone or in combination with critical sanitation controls in HACCP. Significantly, the NACMCF was among those that made this suggestion. NMFS' comment stated that, in its experience, the development of SSOP's by processors in its voluntary program has been associated with marked improvement in sanitation. Many comments stated that much of the seafood processing industry already has SSOP's, and that those that do not should develop them.

FDA agrees that the development by processors of an SSOP would be a beneficial step. FDA therefore is recommending in § 123.11(a) that:

> Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced.

An SSOP places the primary burden for identifying relevant controls on the food processor. To meet this burden, it will be necessary for the processor to think through each operation and identify where, and how frequently, appropriate sanitation measures are necessary. The process of doing so will foster the type of culture that FDA is trying to promote, in which processors assume an operative role in controlling sanitation in their plants.

FDA is adopting § 123.11 pursuant to sections 402(a)(4) and 701(a) of the act to ensure that seafood is not produced under insanitary conditions whereby it may be rendered injurious to health. It grows directly out of proposed § 123.10, but, as stated above, it reflects the agency's efforts to make the sanitation requirements more flexible.

FDA has not elected to make the development of an SSOP mandatory because it recognizes that some processors may be able to achieve satisfactory sanitation conditions and practices without having to commit their sanitation control procedures to writing. The agency remains convinced however, that such satisfactory conditions are unlikely to be achieved without periodic monitoring of the operations. For this reason the agency has retained at § 123.11(b) the mandatory sanitation monitoring requirements proposed at § 123.10(c). Sanitation monitoring will be further discussed in the next section of this preamble.

Where a processor elects to develop an SSOP it should specify how it will meet those sanitation conditions and practices that are to be monitored in accordance with § 123.11(b). These conditions and practices will also be discussed in the next section.

Both § 123.11(d) and § 123.6(f) provide that sanitation controls that are monitored in accordance with § 123.11(b) need not be included in the HACCP plan and vice versa. The purpose of these provisions is to allow processors to incorporate those sanitation controls into their HACCP plans that they believe are appropriately addressed through HACCP, without having to duplicate those controls in a separate sanitation program.

6. Monitoring and Corrective Actions

The regulations no longer contain specific monitoring frequencies to ensure that proper sanitation conditions are being met, as was proposed at § 123.10(c). In keeping with the agency's decision to reduce the prescriptive nature of the sanitation requirements, § 123.11(b) now requires that each processor monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with certain key sanitation conditions and practices as specified in part 110.

112. The agency arrived at this approach in response to the comments. As part of the agency's efforts to achieve flexibility, it examined the 18 sanitation controls that it proposed at § 123.10(a) in light of the comments that argued that they were overly prescriptive. FDA proposed the 18 sanitation controls to ensure that, where relevant to the processing operation, important areas of concern were addressed in each plant. The preamble addressed at some length why each of them was significant and relevant to safety. Moreover, although considerable comment was received that challenged the manner in which a particular processor should address these sanitation conditions and the situations in which they should be considered applicable, only two comments challenged the significance of these conditions or the need for them to be controlled when they are determined to be germane, and neither comment provided a basis for doubting the significance of these controls.

FDA concludes that, where relevant to a processor's operation, the processor should monitor sanitation conditions and practices relating to the general subject areas reflected by the 18 specific sanitation controls because they are important for ensuring the safety of the product. As in the proposal, each processor will be responsible for determining which of the subject areas are relevant to its plant and process. However, unlike the proposal, the