

consumer advocacy groups, State, Federal, and foreign government agencies, and a trade association. Approximately five percent of the comments, from processors, trade associations, and State government agencies, objected to the inclusion of any explicit sanitation controls in these regulations. It is not clear, however, whether the latter comments were objecting to sanitation controls as part of HACCP where appropriate for safety or to any sanitation approach beyond HACCP. The remaining approximately 85 percent of the comments, principally from processors, trade associations, and State and Federal government agencies, generally acknowledged the need for these regulations to address sanitation in seafood processing plants but objected to one or more of the specifics of the proposal.

Those that supported the proposed approach argued that sanitation controls are a critical component of the regulations because: (1) Addressing the insanitary practices in the seafood processing industry is essential to improved consumer confidence; (2) effective sanitation controls are a prerequisite to the proper functioning of a HACCP system; and (3) sanitation controls are critical to the management of microbiological hazards in both products that will not be cooked by the consumer and those that will be cooked, the latter because of the potential for cross-contamination in the kitchen. The comments suggested that a prescriptive approach to sanitation is warranted because the FDA and NMFS inspection results cited in the preamble to the proposal documented the failure of a significant percentage of the industry to control key sanitation conditions and practices. Moreover, these comments continued, the enumeration of specific controls relieves the industry of the burden of identifying the most significant areas of concern.

Several comments stated that sanitation requirements for seafood processors are necessary because guidelines do not have the force of regulation and therefore are more difficult to enforce. One comment stated that including sanitation requirements in these regulations would simplify compliance for seafood processors because the HACCP and sanitation requirements would be in one place. One comment stated that some processors would be more inclined to implement sanitation control measures if all processors were subject to the same mandatory requirements.

Many of the comments that objected to the manner in which FDA proposed to treat sanitation acknowledged that

effective sanitation controls are essential to the proper functioning of a HACCP system. As with comments that supported the proposed approach, a few of these comments identified sanitation as a prerequisite to HACCP.

The comments that objected to the inclusion of any sanitation requirements in these regulations provided reasons that the agency believes are more relevant to the question of how these regulations should address sanitation than to whether they should address the issue. For this reason, the arguments presented in these comments are addressed later in this section.

FDA accepts the view expressed by the overwhelming majority of comments (i.e., those that advocated the proposed approach and those that advocated other sanitation control mechanisms) that sanitation is relevant to the goals of these regulations and should be addressed in them. The primary source of pathogenic microorganisms for most fish (i.e., wild-caught fish) is the processing plant environment (Ref. 3, p. 267). The control of sanitation in the plant is the most effective way to minimize pathogens, and, for products that are not given a final heat treatment after packaging, it is the only way to minimize them at that stage in the chain of distribution (Refs. 3, p. 10; 7, p. 27; 204; and 205). This situation is nearly the reverse of that for red meat and poultry, where pathogens are likely to have originated from the raw materials before they enter the plant (Refs. 36, p. 197; 209; and 210, p. 1).

A significant body of opinion holds, moreover, that good sanitation is a necessary foundation for HACCP. This view was articulated in comments to this rulemaking and in the proposed rule to establish HACCP and other requirements for the beef and poultry industries issued by USDA (Ref. 211). USDA proposed both SOPs for sanitation as a prerequisite to a HACCP plan and sanitation as part of HACCP where critical for safety (Ref. 211, p. 6789).

FDA concludes, therefore, that these regulations cannot fully address all matters relevant to safety, or significantly contribute to the restoration of consumer confidence in seafood without providing for major improvements in sanitation. Therefore, these regulations address sanitation.

3. Why Isn't Part 110 (21 CFR Part 110) Adequate To Deal With Sanitation Concerns?

105. Some comments asserted that it would be adequate to rely on the existing CGMP's in part 110, which provide guidance of general

applicability to all foods. A variation on that concern was the view that the sanitation standards in part 110 need not be codified in these regulations because they are adequately expressed in that part. The NACMCF pointed out that the CGMP's have proven adequate for a wide variety of processed foods under FDA's jurisdiction. Some comments stated that part 110 should be made mandatory for seafood and fully enforced.

Good sanitation is already mandatory for all foods. Section 402(a)(4) of the act deems food to be adulterated if processed under insanitary conditions. The CGMP's in part 110 articulate the kinds of conditions and practices that need to be followed in order to avoid producing an adulterated product under section 402(a)(4) of the act.

Nevertheless, while FDA has been enforcing the sanitation standards contained in part 110 for many years, as indicated earlier, it has not succeeded in developing a culture throughout the seafood industry in which processors assume an operative role in controlling sanitation in their plants. The statistics relating to the incidence of insanitation cited in the preamble to the proposed regulations (Ref. 208 at 4161-4162) clearly demonstrate that such a culture is not adequately in place. The following observation about culture in the preamble to USDA's proposed HACCP rules for beef and poultry is applicable here as well:

* * * Identification of sanitation requirements has been viewed by some establishment owners and personnel as the inspector's responsibility. Such establishments often fail to take the initiative to find and remedy insanitary conditions, relying instead on the inspector to find deficiencies. (Ref. 211, p. 6788)

Moreover, FDA points out that while the CGMP's state that sanitation controls should occur as frequently as necessary, they are silent with regard to monitoring by the processor to ensure for itself that sanitation controls are being followed.

For these reasons, FDA concludes that part 110 alone has not proven to be adequate for the seafood industry. In order to ensure that firms take full responsibility for sanitation in their plants, which is strongly related to the production of safe and wholesome seafood, FDA has concluded that it is necessary to include sanitation requirements in these regulations.

4. Why Isn't the Proposed Approach Appropriate?

106. Many comments that agreed that sanitation should be addressed in the regulations, as well as some that opposed addressing it, objected that the