proposal was too prescriptive. These comments asserted that: (1) The proposed 18 sanitation controls are overly prescriptive and inflexible and are not appropriate for all processors; (2) the codification of prescriptive sanitation requirements as regulations limits the ability of processors to keep pace with advances in science and technology; (3) the proposed sanitation controls have the effect of establishing eighteen CCP's, which are not always appropriate; and (4) the proposed sanitation provisions duplicate or contradict existing State or NSSP requirements. FDA will respond to these criticisms.

Many comments that argued that the 18 specific sanitation controls that FDA proposed were too prescriptive provided examples of how this approach could deny processors the flexibility necessary to develop and implement sanitation programs that are effective for the specific conditions in which they are to be used. Some of these examples are as follows:

(1) A few comments challenged the proposed ''easily cleanable'' standard for equipment, suggesting that in some applications (e.g., at sea processing and old equipment) this standard may not be attainable and may not be necessary as long as the equipment is, in fact, cleaned;

(2) A large number of comments challenged the proposed 4-hour equipment cleaning frequency, suggesting that it is unwarranted in some situations (e.g., refrigerated processing facilities) because it is inconsistent with actual microbiological growth rates. It is unduly burdensome in other situations (e.g., surimi processing facilities), according to the comments, because it would limit shifts to 4 hours, would interrupt production, and would require hours of equipment breakdown time;

(3) A few comments challenged the proposed ''impermeable'' standard for gloves and outer garments that contact food or food contact surfaces, suggesting that in some instances it was impractical (e.g., filleting fish);

(4) A significant number of comments challenged the proposed 4-hour hand sanitizer strength test frequency, suggesting that replacement of dips rather than checking concentration may be appropriate, as may be the use of automated hand washing and sanitizing systems; and,

(5) A number of comments challenged the proposed requirement that hand washing and sanitizing stations be located in processing areas, suggesting that they need only be easily accessible.

These comments have general merit and have persuaded the agency that a less prescriptive approach is appropriate to ensure that the regulations do not impose impractical, unduly burdensome, or excessively rigid requirements.

107. Another concern with FDA's approach was that codifying specific sanitation control procedures would not enable processors to keep their sanitation programs updated with advances in science and technology. As an example, the NACMCF comment cited recent industry experience with other foods that has shown that the proposed requirement of midshift cleaning and sanitizing in packaging rooms for ready-to-eat foods, may with many current sanitation practices actually be counterproductive to the control of *Listeria monocytogenes.* The NACMCF advised that codification of a midshift cleaning requirement would have prevented these industries from modifying their cleaning procedures to adjust to the new information.

FDA agrees that sanitation requirements should be sufficiently flexible to permit the incorporation of new information and better procedures.

108. A number of the comments, including more than half of those that opposed any new form of sanitation controls, argued that the sanitation control approach proposed by FDA would effectively establish eighteen mandatory sanitation CCP's that may not always be appropriate.

These comments may have been the result of a misunderstanding of the relationship between processor HACCP plans and the proposed sanitation controls. While the proposed controls involved monitoring and recordkeeping, they were not proposed as part of a processor's HACCP system. FDA did not intend to designate them as CCP's. FDA believes that the provisions of these final rules make clear that the necessary sanitary controls need not be considered to be CCP's.

109. A large number of the comments that objected to the manner in which FDA proposed to handle sanitation argued that the proposed sanitation provisions are redundant with State and local regulations and, with respect to molluscan shellfish, with the NSSP.

FDA acknowledges that the NSSP and most State seafood control programs include provisions, much like FDA's CGMP's, that are designed to control processing plant sanitation. These other provisions, like the CGMP's, serve as baseline standards for sanitation. However, the rates of noncompliance with existing CGMP standards, as detailed in the preamble to the proposed regulations (Ref. 208 at 4161–4162), demonstrate a need for a system in which processors are responsible for not only meeting these baseline standards but also routinely auditing their facilities and operations to ensure that they are meeting them. In this way, the sanitation requirements of these regulations build upon existing sanitation requirements, at the Federal, State, and local levels.

The more generalized nature of these final regulations with respect to sanitation should mitigate the concerns of the comments that complained about the conflict between, and duplication with, existing sanitation standards.

As discussed elsewhere in this preamble, FDA encourages adoption of these regulations by State and local regulatory agencies. FDA is convinced that, in many cases, the regulations can be quite easily overlaid on existing State, local, and NSSP requirements.

5. What Is the Appropriate Approach to Sanitation?

Based on its review of the comments, FDA has been convinced that a modification of its approach to sanitation is appropriate. FDA concludes that its approach in the proposal was too inflexible and could have made it more difficult in certain circumstances to incorporate new technologies and information.

The comments argued for one or more of several approaches that they identified as being more appropriate than FDA's proposed approach: (1) Requiring that each processor develop and follow a SSOP that is specifically tailored to a processing operation; (2) including sanitation controls in the HACCP plan where they are critical to product safety; and (3) retaining the general approach of the proposed regulations but somehow reducing the number of specific requirements. Approximately 85 percent of those that opposed the way that sanitation was treated in the proposal advocated one or a combination of the first two of the approaches, with the recommendations evenly split between the two. The small number of comments that objected to including any specific sanitation requirements in the regulations may also have been arguing that sanitation should not be part of HACCP but should be controlled solely through CGMP's.

a. *Inclusion of sanitation controls in HACCP plans.*

110. There was strong support in the comments for the inclusion of sanitation controls in HACCP plans, particularly where the controls are necessary to protect the safety of the product. The comments stated that a processor's