processor will be free to tailor the sanitation controls to the circumstances of its operation, as long as it does so in a manner that ensures the effectiveness of those controls. The regulations do not specify the manner in which control must be achieved. FDA will provide guidance on how to ensure appropriate sanitation control in the Guide. FDA is deferring consideration of the comments that it received on the specific sanitation control measures that it described in the proposal until it prepares the Guide.

In order to ensure that processors monitor the general subject areas reflected by the 18 specific sanitation controls listed in the proposal, FDA has concluded that it is appropriate to list in the regulations the sanitation controls that should be considered. This list will ensure that the most significant sanitation controls are considered by the processor in formulating the measures that it will institute in its plant.

The controls that FDA is listing in § 123.11(b) no longer contain sanitation standards that are beyond part 110 or repeat specific standards that are contained in that part. Instead, § 123.11(b) now states that the processor shall ensure that actions are taken to ensure that those sanitary conditions that are contained in part 110 and that are relevant to the plant are maintained in eight general areas:

(1) The safety of the water that comes into contact with food or food contact surfaces or is used in the manufacture of ice (\S 123.11(b)(1)). This control derives from proposed \S 123.10 (a)(1) and (a)(2) relating to water quality and treatment and to cross connections between potable and nonpotable water systems.

Water is used in virtually all seafood processing facilities for washing product, equipment, and employees' hands, for transporting fish in flumes, and as an ingredient. Contaminated water can serve as a vehicle for contamination of the product, both directly and indirectly (Refs. 63; 64; 65, p. 49; 66; 67; and 68, pp. 1 and 2). Cross connections, which include situations that allow for back siphonage into a potable system from a nonpotable system under negative pressure conditions, can result in the chemical or microbiological contamination of the potable water system (Refs. 64; 65, pp. 50 and 51; 68; 71; and 72).

This matter was one of the two, as indicated above, about which FDA received a comment that challenged the need for a sanitation control. A comment suggested that the safety of the water supply is within the jurisdiction of local health authorities, and that a processor should not have to deal with that issue.

FDA acknowledges that many State and local jurisdictions exercise control over both public and private water supplies. In the case of private wells, they often permit and inspect the construction of the well and collect periodic water samples for microbiological and chemical attributes. Where such is the case, it may be reasonable for the processor to rely upon these measures. However, in the absence of appropriate controls by a public authority, FDA has concluded that the processor must exercise whatever control is necessary to ensure that the water supply is safe. To do otherwise would be to subject the product to an unacceptable safety risk from the contaminants that may be introduced by the water.

(2) The condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments (§ 123.11(b)(2)). This control derives from proposed § 123.10 (a)(3) through (a)(5) relating to the design, workmanship, materials, and maintenance of food contact surfaces; the cleaning and sanitizing of these surfaces, including the frequency of cleaning and sanitizing; the impermeability of gloves and outer garments that contact food; and the maintenance of gloves and outer garments.

Utensils, equipment, aprons, gloves, outer garments, and other food contact surfaces can be vehicles for microbial contamination of both the raw and finished products. Food contact surfaces that contain breaks, pits, cuts, or grooves, or that are porous or corroded, may harbor pathogenic microorganisms that can migrate to the product and contaminate it. These kinds of surfaces are difficult to clean (Refs. 65, pp. 20, and 36-48; 72, pp. 166-167; 73; and 83). Where food contact surfaces are constructed of toxic materials, the product may be directly contaminated (Ref. 74). Inadequately cleaned food contact surfaces can serve as a reservoir for pathogenic microorganisms, especially if biofilms are allowed to form, in which microorganisms can be entrapped and shielded from the action of cleaning and sanitizing compounds.

(3) The prevention of crosscontamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product (§ 123.11(b)(3)). This control derives from proposed § 123.10 (a)(6), (a)(7), (a)(13), and (a)(18), relating to employee practices to prevent contamination, to physical separation of raw and cooked product, and to plant design to prevent contamination.

Employees and food contact surfaces can serve as vectors in the transmission of pathogenic microorganisms to the food. These microorganisms can be introduced to the product from outside areas, rest rooms, contaminated raw materials, waste or waste receptacles, floors, and other insanitary objects. In the processing of cooked products, the raw material may also serve as a reservoir of pathogenic microorganisms. Employees or equipment that touch the raw material can transmit these microorganisms to the cooked product (Refs. 7, 63, 64, 73, 74, 84, and 85). Finally, proper construction of the processing plant is essential if other sanitary measures are to be successful. For example, incompatible operations, such as handling of raw materials and handling of cooked product, should be isolated (Refs. 71, 74, 87, and 88).

(4) The maintenance of hand washing, hand sanitizing, and toilet facilities (§ 123.11(b)(4)). This control derives from proposed § 123.10 (a)(8) and (a)(16), relating to the location and maintenance of hand washing and sanitizing facilities, and toilet facilities.

Employee's hands can serve as a vector for the transmission of pathogenic microorganisms to the food. Hand washing and sanitizing, when performed using suitable preparations are effective means of preventing such transmission. Toilet facilities eliminate from the processing environment pathogenic microorganisms shed in fecal material (Refs. 63, 64, 73, 74, 84, and 85).

(5) The protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants (§ 123.11(b)(5)). This control derives from proposed § 123.10(a)(9), (a)(11), and (a)(12), relating to the protection of food from various microbiological, chemical, and physical contaminants.

The use of toxic compounds (e.g., pesticides, cleaning and sanitizing agents, and lubricants) is frequently necessary in the processing environment. Food and food packaging materials should be protected or removed from areas where pesticides are used, and caustic cleaning compounds should be thoroughly removed from food contact surfaces before processing begins (Ref. 74). Condensate which forms on an insanitary surface and then falls on the