product may carry with it pathogenic microorganisms (Ref. 65, pp. 24–25).

This measure is the second about which FDA received a comment that challenged the value of having a sanitation control. A comment suggested that preventing the formation of condensate on ceilings above processing is, in some situations, physically impossible. The comment did not suggest that condensate is irrelevant to safety.

FDA reasserts that condensate is relevant but acknowledges that there are instances in which it may be impractical for it to be fully eliminated. In these instances, after taking all reasonable measures to minimize the development of condensate, the processor will need to take steps to protect the product from the dripping condensate or to ensure that the surface from which it is dripping is sanitary. The development of a written SSOP processor should tailor its sanitation controls to its particular situation in order to accomplish this objective.

(6) The proper labeling, storage, and use of toxic compounds (§ 123.11(b)(6)). This control derives from proposed § 123.10(a)(10), relating to the overall handling of toxic compounds to protect against contamination of food. Improper use of toxic compounds is a frequent cause of product adulteration throughout the food industry. Proper labeling, storage, and use of the compounds is necessary to minimize the risk of occurrence of such incidents (Ref. 74).

(7) The control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces (§ 123.11(a)(7)). This control derives from proposed § 123.10(a)(15), relating to the exclusion of persons who appear to have an illness, wound, or other affliction that could be a source of microbial contamination.

Employees can serve as a reservoir of diseases, such as salmonellosis, shigellosis, and hepatitis, that can be transmitted to consumers by foods. Additionally, open sores, boils, or infected wounds present the potential for contamination of the food with such pathogenic microorganisms as *Staphylococcus aureus* (Refs. 22, 74, and 84).

(8) Exclusion of pests from the food plant (§ 123.11(b)(8)). This control derives from the proposed requirements at § 123.10(a)(17). Pests, such as rodents, birds, and insects carry a variety of human disease agents, which they can introduce to the processing environment (Refs. 63, 64, 73, and 84).

113. FDA proposed at § 123.10(a)(14) that, ''Refrigeration units that store raw materials, in-process, or finished fish or fishery products that are cooked, ready-to-eat, smoked, or made in whole or in part from scombroid toxin forming species shall be operated at a temperature of 40 °F (4.4 °C) or below.'' The purpose of the proposed requirement was to ensure that processors control the microbiological hazards associated with refrigerated storage for these particularly susceptible products. A significant number of comments argued the control of temperature in refrigerated storage is a processing hazard rather than a sanitation issue, and should be covered by a firm's HACCP plan.

FDA agrees with these comments and has not included a provision on refrigeration in the sanitation section of these regulations. A large number of comments were received relative to the appropriateness of a 40 °F (4.4 °C) limit. These comments are no longer relevant to these regulations but will be addressed in the redrafting of the Guide.

FDA has also incorporated the corrective action requirement relative to sanitation conditions proposed at § 123.10(d) in § 123.11(b). Section 123.11(b) the processor shall, correct in a timely manner those sanitation conditions and practices that are not met. The phrase ''in a timely manner'' did not appear in the language of proposed § 123.10(d). However, it was implicit that corrections should be made as quickly as possible so as not to subject subsequently processed product to conditions that could both jeopardize their safety and render them adulterated. FDA has added the phrase for clarity.

Note that the other corrective action requirements in these regulations, i.e., those in § 123.7, do not apply to sanitation controls that are exclusively addressed in § 123.11. The controls in § 123.7 apply to a processor's HACCP system only.

7. Records

114. FDA received approximately 20 comments that addressed the issue of sanitation records. Many others discussed recordkeeping in general but did not specifically mention records of sanitation controls. These latter comments have already been addressed in the ''Records'' section of this preamble.

Of those that commented specifically on sanitation records, approximately three-fifths, from processors and trade associations, objected to the proposed requirement that processors maintain records that demonstrate compliance with the appropriate sanitation standards. In fact, a number of comments listed this issue as a significant reason for their objection to the overall proposed approach to sanitation control. The comments suggested that sanitation recordkeeping is costly and has not been demonstrated to be effective. None of these comments provided any data in support of their statements. Some argued that, while they accepted the notion of records for CCP monitoring, they opposed records of sanitation monitoring.

The remaining comments that addressed the issue of sanitation records, from consumer advocacy groups, an individual, a Federal government agency, a trade association, and a seafood broker, supported the need for such records. These comments argued that sanitation records are essential to ensure that processors adhere to established sanitary standards, and that they need not be extensive.

FDA does not find the arguments against the requirement for sanitation control records to be compelling. The agency concludes that the burden will be minimal. Checklist type or simple notation records will suffice in most instances. Creating them should be incidental to monitoring. Monitoring to ensure that sanitation is under control is the responsibility of all processors.

Monitoring and recording of sanitation conditions is as much a key to the success in improving those conditions, and, hence, to increasing consumer confidence in the seafood processing industry, as is the development by a processor of an SSOP. As in the case of HACCP records, sanitation records require that processors engage in systematic monitoring of their own sanitation practices and conditions. It enables them to see trends. Moreover, participation in recordkeeping helps empower the work force and foster responsibility. It also allows the regulator to assess a processor's compliance over a period of time, not just at the time of an inspection.

FDA believes that the records bearing on the monitoring of relevant sanitation conditions and practices and FDA's access to such records are all essential if § 123.11 is to be an effective regulatory strategy. Therefore, FDA has concluded that the recordkeeping requirement proposed at § 123.10(b) will be retained. To reflect other modifications in this section, § 123.11(c) has been modified to read, ''Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b)