SGR 119

Seafood HACCP Alliance Course

Sanitation Control Procedures for Processing Fish and Fishery Products

Developed by the National Seafood HACCP Alliance for Training and Education.

First Edition 2000

NATIONAL SEAFOOD HACCP ALLIANCE

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Florida Sea Grant Report -119.

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ATTENTION READERS (March 2017)

This edition of *Sanitation Control Procedures for Processing Fish and Fishery Products* (SGR 119, First Edition 2000), developed by the National Seafood HACCP Alliance, remains the recognized curriculum that accompanies Sanitation Control Procedures certificate courses offered through the Association of Food and Drug Officials in accordance with the Seafood HACCP Protocol.

Over the years the Seafood HACCP Alliance has assessed whether or not to update this book and each time has decided "no." While some of the technical background information may have evolved, this is not a basic sanitation manual. The purpose of this training is to assist processors in developing and implementing Sanitation Control Procedures as mandated by the U.S. Food and Drug Administration Seafood HACCP regulation (21 CFR 123.11). FDA's expectations of compliance with 123.11 have not changed over the years; therefore the materials addressing the main purpose of the training have not required updating.

Recently however, FDA has updated the Current Good Manufacturing Practice regulations, or GMPs, as part of a broader modernization of food safety regulations. By 2018, 21 CFR Part 117 – Subpart B-Good Manufacturing Practices will replace 21 CFR Part 110 Good Manufacturing Practices. (Implementation of the changes has been phased in since 2016 depending on the size of the firm.)

Please be advised that the regulations cited as 21 CFR 110 have been changed to 21 CFR 117, Subpart B. Any reference in this book to 21 CFR 110 should be adjusted to the appropriate section in 117. The table below provides the corresponding adjustment. A reprint of the revised GMP regulation is also available in Appendix 3 of the newly revised *Hazard Analysis and Critical Control Point Training Curriculum*, the Seafood HACCP Alliance "Blue Book." The regulation is also available at **www.gpo.gov.**

Old 21 CFR 110	New 21 CFR 117 – Subpart B
§ 110.3 Definitions	§ 117.3 Definitions
§ 110.5 Current good manufacturing practice	§ 117.1 Applicability and status
§ 110.10 Personnel	§ 117.10 Personnel
§ 110.20 Plant and grounds	§ 117.20 Plant and grounds
§ 110.35 Sanitary operations	§ 117.35 Sanitary operations
§ 110.37 Sanitary facilities and controls	§ 117.37 Sanitary facilities and controls
§ 110.40 Equipment and utensils	§ 117.40 Equipment and utensils
§ 110.80 Processes and controls	§ 117.80 Processes and controls
§ 110.93 Warehousing and distribution	§ 117.93 Warehousing and distribution
	§ 117.95 Holding and distribution of human food by-products for use as animal food
§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard	§ 117.110 Defect action levels

Impact of GMP revisions to Seafood HACCP and Sanitation Control Procedures

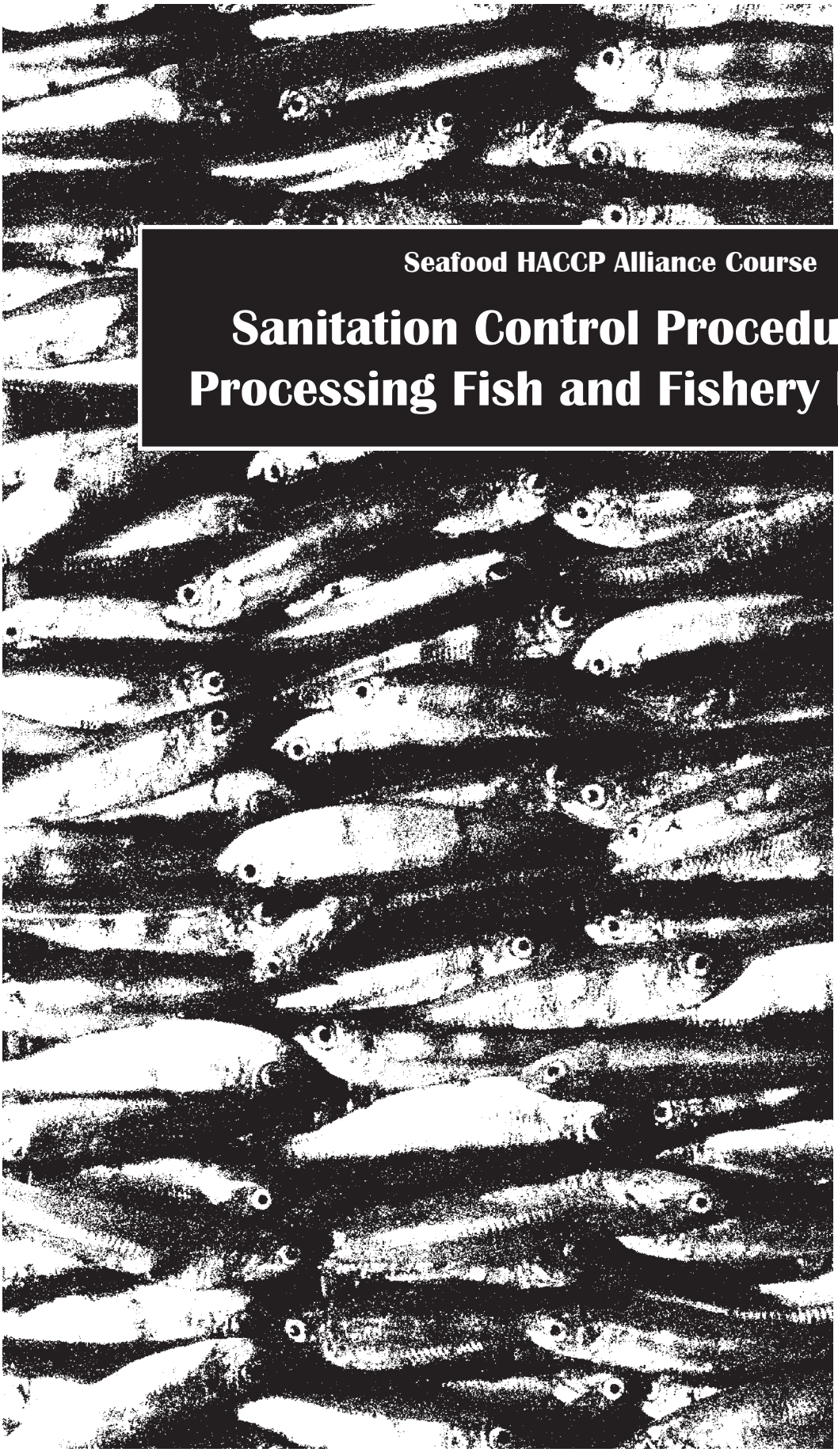
One notable change in the GMPs is that FDA's longstanding position that GMPs address the prevention of allergen cross-contact is now explicit in the revised regulatory text. The agency has made a distinction between "cross-contamination" and "cross-contact."

Cross-contact – unintentional incorporation of food allergens into food.

Cross-contamination – contamination of food with bacterial, chemical or physical hazards.

Controls addressing allergen cross-contact may be incorporated into aspects of sanitation control procedures that are the subject of this training curriculum. Chapter 2 of the Seafood HACCP Alliance Blue Book curriculum demonstrates the relationship between the GMPs and 21 CFR 123.11 – Sanitation Control Procedures. Examples of updated monitoring forms are also available in Chapter 2 of the Blue Book.

Technical information on developing allergen cross-contact prevention programs is widely available through publications and websites.



Seafood HACCP Alliance Course

Sanitation Control Procedures for Processing Fish and Fishery Products

Developed by the National Seafood HACCP Alliance for Training and Education.

First Edition 2000

Foreword
National Seafood HACCP Alliance

The National Seafood HACCP Alliance for Education and Training is simply a cooperative effort amongst existing industry and government programs sharing their responsibility to advance the safety of seafood products in the United States, be they harvested, aquacultured or imported. Their approach is to provide uniform education through courses designed for the diverse commercial sectors and the corresponding inspection authorities. The courses are further complimented with a "Compendium of Fish and Fishery Product Processes, Hazards, and Controls" and the FDA's "Fish & Fishery Products Hazards & Control Guide." All training materials are not restricted and are made available for public and international use.

Following the initial project grant from the National Sea Grant College Program in 1993, the Seafood HACCP Alliance is now supported by a tripartite of funds from the U.S. Food and Drug Administration, the Association of Food and Drug Officials and the National Sea Grant Office for educational activities through 2001. Their efforts are still recognized by "Certificates of Course Completion" that are issued and recorded by the Association of Food and Drug Officials based in York, Pennsylvania. The Alliance activities, educational material and scheduled courses are posted on their adopted website, http://seafood.ucdavis.edu.

The Seafood HAACP Alliance does not have regulatory authority and it does not address or set regulatory policy for food safety. Their educational plan recognizes the essential role of state regulatory authorities, the educational networks of Sea Grant and Cooperative Extension Services, the respective federal agencies and the industry trade association in providing current and continuous educational support for commerce and public interests.

SPECIAL NOTE: Although the Seafood HACCP Alliance does not enforce or set regulatory policy, their editorial committees do provide recommendations through examples in their curricula that are intended to help firms comply with the prevailing regulations. These recommendations should not be considered regulatory requirements. The training materials try to distinguish specific regulatory requirements through references to the rules or authorities.

Seafood HACCP Alliance Training Materials

Sanitation Control Procedures for Processing Fish and Fishery Products, First edition January 2000, 203 pages. Manual available from Florida Sea Grant College Program, P.O. Box 110409, Gainesville, FL 32611-0409 (352) 392-2801.

HACCP: Hazard Analysis and Critical Control Point Training Curriculum, Third Edition (English) July 1996, 276 pages, and Second Edition, 1997 (Spanish), UNC-SG-98-07. Manual available bound - North Carolina Sea Grant, Box 8605, NC State University, Raleigh, NC 27695-8605 or call 919/515-2454.

Fish & Fishery Products Hazards & Control Guide, Second Edition, January 1998, 276 pages. Manual available bound-North Carolina Sea Grant, Box 8605, NC State University, Raleigh, NC 27695-8605 or call 919/515-2454. Send inquiries to U.S. Food & Drug Administration, Docket Management Branch (HFA-305), Room 1-23, 12420 Parklawn Drive, Rockville, Maryland 20857 for docket number 93N-0195.

Compendium of Fish and Fishery Product Processes, Hazards and Controls (continuous updates) available website - http://seafood.ucdavis.edu/haccp/compendium/compend.htm

Future Editions

This manual, future additions and the latest updates are available at the following website:

http://seafood.ucdavis.edu/sanitation/scpmanual.htm

Seafood HACCP Alliance Course

Sanitation Control Procedures for Processing Fish and Fishery Products

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Seafood HACCP Alliance Course

Sanitation Control Procedures for Processing Fish and Fishery Products

Introduction

This course is intended to assist the seafood industry in developing and implementing 'Sanitation Control Procedures' as mandated by the U.S. Food and Drug Administration (FDA). This regulation is commonly known as the "Seafood HACCP Regulation" which became effective December 18, 1997. Since this date, seafood processors have been required to 'monitor' sanitary control procedures used during processing in order to show their conformance with good sanitary conditions and practices. Likewise, seafood importers must verify that the seafood being imported was processed in accordance with the same FDA mandated HACCP requirements that include sanitation monitoring procedures and records. This is a new and challenging regulatory approach which will require understanding and cooperation by all levels of the seafood industry and the respective inspection authorities.

I-1. **Course Purpose:**

To assist industry in developing and implementing Sanitation Control Procedures as mandated by FDA's "Seafood HACCP Regulation" (21CFR, Parts 123 & 1240).

Course Objectives:

- How to develop Sanitation Standard Operating Procedures (SSOP);
- How to conduct monitoring for sanitary "conditions and practices"; and
- How to maintain sanitary conditions and practices.

FDA

Course Application

This Sanitation Control Procedures training will apply to fish and fishery product processing defined as:

Fish, which means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds and mammals, and all mollusks, where such animal life is intended for human consumption;

Fishery product, which means any human food product in which fish is a characterizing ingredient; and

Processing which, with respect to fish and fishery products, means; handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

Processing as defined by the seafood HACCP regulations does not apply to:

* Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
* Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on-board a harvest vessel.
* The operation of a retail establishment.

Course Content

Rather than a basic food sanitation course, this training format features the regulatory requirements for monitoring sanitary conditions and practices, encourages development of written SSOP, and offers background information on basic sanitation.Course participants should learn how to draft SSOP plans and build sanitation monitoring programs to address eight key sanitary conditions. Proper plans and monitoring should lead to proper practices. Background information is provided to assist in developing proper sanitary practices. Course completion is only a start. The primary measure of success will be based on in-plant performance.

I-2. Elements of the Course:

1. Sanitation Standard Operating Procedures (SSOP);
2. Sanitation Monitoring and Corrections; and
3. Basic Sanitation in Processing.

The course includes a chapter for each of the eight key sanitation conditions or areas specified by the FDA Seafood HACCP Regulations. Each of these course chapters are organized in three parts -- 1) required sanitation monitoring, corrections and records; 2) related background information on sanitation; and 3) example sanitation control guides.

I-3. Course Chapters –3 Parts:

1. Sanitation monitoring, corrections and records;
2. Background information on sanitation; and
3. Sanitation Control Guides (examples).

I-4. Course Agenda -- Sanitation Control Procedures

8:00 a.m.	Registration and Welcome
8:30 a.m.	Introduction
9:30 a.m.	Safety of Water
10:00 a.m.	Break
10:30 a.m.	Condition and Cleanliness of Food Contact Surfaces (two parts)
	Lunch
1:15 p.m.	Prevention of Cross-Contamination
1:45 p.m.	Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities
2:15 p.m.	Protection of Food from Adulterants and Proper Labeling, Storage and Use of Toxic Compounds
2:45 p.m.	Break
3:15 p.m.	Control of Employee Health Conditions
3:45 p.m.	Exclusion of Pests
4:15 p.m.	Example of SSOP Plan and Sanitation Control Records
	Adjourn

The chapters progressively build and explain a typical monitoring form for both daily and monthly sanitation control records. The recording form used is taken from the Seafood HACCP Alliance's "Encore" HACCP course to illustrate a variety of considerations in designing a monitoring record. The particular "Encore" Training form is not required to comply with the federal HACCP mandate, but it does include features that processors should consider in developing monitoring forms for their specific processing operations.

The course offers a variety of monitoring forms to illustrate approaches to customizing the sanitation records to suit particular processing operations. Although, there are no federally mandated frequencies for sanitation monitoring for either daily or periodic records, the course suggests frequencies in monitoring that would satisfy conformance with the conditions and practices specified in the Good Manufacturing Practices (GMP). Frequency for monitoring must be appropriate to the plant and food being processed.

The chapters conclude with example "Sanitation Control Guides" that can be referenced when developing a sanitation monitoring program (I-6). The Sanitation Control Guides are **not** specified regulatory requirements. They are simply provided as a guide or reference. Each guide deals with one of the eight key sanitary conditions. These guides identify key sanitation concerns and provide examples of problems and issues often encountered in processing. They list recommended controls, monitoring procedures and corrections. The listed frequencies for monitoring are only recommendations which may vary for particular processing conditions and foods. In most of the chapters, more than one Sanitation Control Guide is provided because a variety of plant procedures may affect any one of the eight key sanitation conditions.

The Sanitation Control Guides are not SSOP per se, but may be used as a foundation for developing company-specific SSOP. Sanitation Standard Operating Procedures should clearly list company procedures for complying with the sanitation monitoring requirements of the FDA Seafood HACCP regulation and the Good Manufacturing Practices (Appendix). A firm's SSOP should include step-by-step details, such as describing the type of sanitizers used, where they are used, how they are applied, when they are applied, and in what concentrations. A simple example of a complete SSOP plan is provided in the last chapter, "Example SSOP Plan and Sanitation Control Records." It contains a monitoring form that is formatted differently than the example used in other parts of the course. This illustrates the need to use a form that matches each company's SSOP. Regardless of the approach, any resulting SSOP plan should reflect the procedures and character of the particular processing operation.

I-5. Frequency for Monitoring

Frequency for monitoring sanitation practices and conditions are not specified in the FDA Seafood HACCP Regulations, but are recommended in this Alliance course as an optional guideline to help ensure conformance with the Good Manufacturing Practices (GMP) that should be appropriate to the plant and food being processed.

I-6. Example Sanitation Control Guide

Sanitation Control Guide		
Entry date:	Cleaning and Sanitizing	FDA Key Condition No. 2

Concern: Food contact surfaces may appear clean but harbor pathogens

Examples:

Bacteria may be present in crevices, overlapping joints or hidden areas difficult to inspect. Clearly visible surfaces may be coated with invisible biofilms containing bacteria. Some surfaces may be stained with minerals or water scale making visual inspection difficult. Chemicals used for cleaning and sanitizing must be appropriate and effective without harming the equipment, utensils or environment of discharge.

Controls and Monitoring:

Visual check of all food contact surfaces for proper cleaning and sanitation. Use a strong flashlight or other shadow-free lighting source when inspecting hidden areas. Disassemble and inspect food contact equipment to identify areas which may trap soils. **Frequency: Daily pre-op for raw seafood line, plus after every break for ready-to-eat line.**

Confirm visual checks with bacterial contact plates or luminometer. **Frequency: Monthly or more frequently if results indicate.** (Note: swabs are used in place of contact plates in areas that are difficult to access). Luminometer — weekly or more frequently if results indicate.

Visually confirm that proper procedures, equipment and chemicals are used for cleaning and sanitizing. Use five-step approach. Use test papers to record proper strength for sanitizers. **Frequency: Daily pre-op for raw seafood line, plus after every break for ready-to-eat line.**

- Pans, knives, and other utensils are placed in a soak tank containing general purpose detergent (concentration controlled by proportioner). After soaking 30 mins. the items are rinsed and dipped in sanitizer (100 ppm chlorine).
- All processing waste removed from work areas, and tables and floors are dry cleaned. Tables are cleaned with general purpose detergents followed by rinsing then exposure to 200 ppm chlorine. Floors, splash zone of walls (4 feet above floor), and sinks are cleaned then sanitized with 400 ppm quats or 200 ppm chlorine.
- Periodically (weekly) use an acid detergent to remove stains and scale
- Periodically switch (monthly) to another class of sanitizer to prevent selecting tolerant types of microorganisms.

Recommended Corrections:

If surfaces are inadequately cleaned, fully reclean and resanitize following the five-step procedures. Check sanitizer concentrations. Train employees semiannually or more frequently if indicated by monitoring.

Records:
Daily Sanitation Control Record
Contact Plate Record (confirmation)
Employee Training Record

Sanitation Control Procedures in the HACCP Regulation

The Seafood HACCP Regulation recommends ("should") that each processor have and implement written Sanitation Standard Operating Procedures (SSOP), and requires ("shall") that they monitor the sanitary conditions and practices during processing. In turn, many states have adopted this regulatory approach and it is a recognized requirement for interstate and international commerce. This FDA regulation is specifically referenced as Title 21 in the Code of Federal Regulations (CFR), Parts 123 and 1240 (21 CFR, Part 123 & 1240), "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products." This regulation became effective December 18, 1997. The specific wording from the regulation is provided in the Appendix. A review of the rule is provided in Chapter 12, "The Seafood HACCP Regulation" in the Alliance's HACCP: Hazard Analysis and Critical Control Point Training Curriculum (see Chapter References). The CFR and Alliance Chapter should be referenced to better understand the basic HACCP requirements.

I-7. Sanitation Control Procedures are an integral part of the Seafood HACCP Regulation:

1. Processors 'should' have and implement a written SSOP plan;
2. Processor 'shall' monitor the sanitary conditions and practices;
3. Processors "shall" correct insanitary conditions and practices in a timely manner; and
4. Processors "shall" maintain sanitation control records.

FDA included sanitation control procedures as an integral part of the seafood HACCP regulations to encourage processors to pay more attention to routine sanitary practices. FDA felt the additional controls were necessary because:

-sanitation practices directly affect the microbiological safety of seafood products that are not further cooked by the consumer, such as, ready-to-eat products, smoked products, raw molluscan shellfish, and other fish that are consumed raw;

-sanitation practices are relevant to the microbiological safety of seafood products even where these products are to be cooked by the consumer;

-sanitation practices directly affect the chemical and physical safety of seafood products;

-nearly half of the consumer complaints that FDA receives relating to seafood are related to the processing plant or food hygiene; and

- inspections conducted by FDA and the National Marine Fisheries Service (NMFS) demonstrate that a significant portion of seafood processors operate under poor sanitation conditions.

According to existing laws, any food processed under 'insanitary' conditions is adulterated because the food may be contaminated with filth, or substances that could render the food injurious to health [Food Drug & Cosmetic Act, section 402(a)(4)]. The current Good Manufacturing Practice (GMP) regulations were issued (Chapter 21 CFR Part 110) to help prevent these problems. These GMP have been and continue to be applicable to all foods including fishery products. They outline the basic conditions and practices that must be followed in order to avoid adulteration. A complete copy of these regulations is contained in the Appendix.

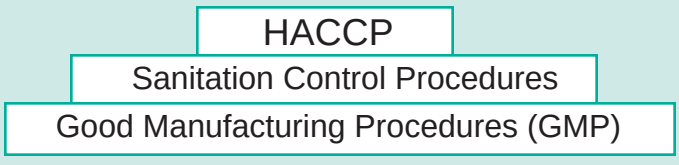
The new mandated sanitation control procedures focus on specific parts of the GMP. They introduce new requirements for monitoring, corrections, and recordkeeping that are not specified in the GMP. The HACCP-like features for monitoring and record keeping were considered necessary "to develop a culture throughout the seafood industry in which processors assume an operative role in controlling sanitation in their plants." In other words, application of the existing GMP across the seafood industry in both domestic and international settings was not evident at sufficient levels to advance seafood safety. Monitoring and recording were deemed necessary to encourage appropriate sanitary conditions and practices on a more routine basis.

I-8. Why Monitor Sanitation Control Procedures?

" . . . to develop a culture throughout the seafood industry in which processors assume an operative role in controlling sanitation in their plants."

Together the sanitation control procedures and GMP form the foundation for a complete seafood safety program topped with a HACCP program that is product and process specific. HACCP cannot succeed in a plant that does not have adequate GMP.

I-9. Food Safety Control Program



CCP vs. Sanitation Control Procedures

A complete food safety program includes both a HACCP plan and the accompanying sanitation control procedures based on GMP. Both components require monitoring, corrections and recordkeeping, yet there are a few regulatory subtleties that should be distinguished for each component.

The HACCP plan for seafood safety is built on a hazard analysis that reveals specific critical control points (CCP) that must be monitored to ensure that a processing step or procedure is in control so as to prevent, eliminate, or reduce to an acceptable level, any potential food-safety hazard. The written HACCP plan specifies the various CCP for a particular process and details the critical limits, monitoring methods, corrective actions, verification procedures and records to be used to assure that control is maintained at a CCP.

I-10.

CCP: A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Sanitation Control Procedure: Procedure to maintain sanitary conditions usually related to the entire processing facility or an area, not just limited to a specific processing step or CCP.

Some hazards are best controlled through sanitation control procedures. Relegating control of a hazard to sanitation control procedures rather than HACCP does not minimize its importance. It simply may be the most appropriate means of control. Frequently, both HACCP and sanitation control procedures are necessary to control a hazard. For example, under HACCP a critical control point is implemented at a smokehouse to make sure sufficient heat is applied to kill potential pathogenic bacteria. Sanitation monitoring to ensure proper employee hygiene and plant sanitation is necessary to minimize the potential for recontaminating the product after smoking.

I-11. **Identified hazards . . .**

. . . which are inherent to the product or are associated with a discrete processing step must be controlled with HACCP. Hazards associated with the processing environment or personnel are usually better controlled with sanitation control procedures.

Identified hazards which are inherent to the product or are associated with a discrete processing step must be controlled with HACCP. Hazards associated with the processing environment or personnel are usually better controlled with sanitation control procedures. Sanitation monitoring can be used to control hazards associated with the eight sanitation areas listed in the HACCP regulation and covered in this course. Use HACCP to control product and process-related hazards identified in FDA's Fish and Fishery Products Hazards and Controls Guide. Some examples of these distinctions are provided in Table I-12.

I-12. Differentiating HACCP and Sanitation Control Procedures

Hazard	Control	Type of Control	Control Program
Histamine	Time & temperature of scombroid fish	Product specific	CCP
Pathogen Survival	Time & temperature for smoking fish	Processing step	CCP
Contamination with pathogens	Wash hands before touching product	Personnel	Sanitation
Contamination with pathogens	Limit employee movement between raw and cooked areas	Personnel	Sanitation
Contamination with pathogens	Clean and sanitize food contact surfaces	Plant environment	Sanitation
Chemical contamination	Use only food-grade grease	Plant environment	Sanitation

The distinction between CCP and sanitation control procedures is not always clear. For this reason, the Seafood HACCP regulation allows sanitary controls for safety to be included in the HACCP plan. In most situations, processors should not complicate the HACCP plan with sanitation monitoring requirements that would be better served in sanitation control procedures. It would be difficult to assign and meet critical limits and corrective actions for certain sanitation controls and excessive sanitation monitoring assigned at CCP could burden the HACCP plan and detract attention from critical processing procedures. Sanitary conditions usually relate to the entire processing facility or an area, not just to a limited or specific processing step or CCP. In some instances, a seafood processing operation may not require a specific HACCP plan because the hazard analysis revealed no significant hazards, yet all processing firms must always monitor for sanitary conditions and practices.

Specific Sanitation Control Regulations

I-13. Recommended SSOP Plan:

"Each processor 'should' have and implement a written SSOP or similar document that is specific to each location where fish and fishery products are produced."

21 CFR, Part 123.11(a)

A written SSOP plan explaining the sanitation concerns, controls, in-plant procedures and monitoring requirements is recommended, but not required by the FDA seafood HACCP regulation. This course encourages development and use of written SSOP plans and offers sanitation guidelines.

I-14. SSOP plans:

- ✓ Describe the sanitation procedures to be used in the plant;
- ✓ Provide a schedule of these sanitation procedures;
- ✓ Provide a foundation to support a routine monitoring program;
- ✓ Encourage prior planning to ensure that corrections are taken when necessary;
- ✓ Identify trends and prevent recurrent problems;
- ✓ Ensure that everyone, from management to production workers, understands sanitation;
- ✓ Provide a consistent training tool for employees;
- ✓ Demonstrate commitment to buyers and inspectors; and
- ✓ Lead to improved sanitation practices and conditions in the plant.

I-15. Sanitation Monitoring Program

"Each processor 'shall' monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with these conditions and practices specified in the [GMP] that are appropriate to the plant and food being processed."

21 CFR, Part 123.11(b)

In developing the seafood HACCP regulation, FDA used findings from previous regulatory inspections and consumer complaints to determine the most common sanitary problems. The results, based on inspections during 1991 - 1992 for nearly all domestic manufacturers in the FDA inventory of seafood establishments, indicated that some processing firms had problems with general sanitation conditions in the processing area. For example, processing firms:

- did not clean and sanitize their processing areas or equipment throughout the day's production;

- had employees that were not following proper sanitation practices in processing, packaging, or finished product storage activities;

- lacked hand sanitizers in their processing area or had sanitizers that were not kept at proper sanitizing levels.

FDA combined their concerns into eight (8) areas of sanitation. This training program is built around these eight key areas of sanitation to be discussed in training as the EIGHT KEY SANITATION CONDITIONS.

I-16. FDA's Eight Key Sanitation Conditions

1. Safety of the water that comes in contact with food or food contact surfaces, or is used in the manufacture of ice;

2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

3. Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and other outer garments, and from raw product to cooked product;

4. Maintenance of hand washing and sanitizing, and toilet facilities;

5. Protection of food, food packaging materials, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

6. Proper labeling, storage, and use of toxic compounds;

7. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

8. Exclusion of pests from the food plant.

Source: FDA Seafood HACCP Regulation, 21 CFR, Part 123.11

Monitoring will provide the required sanitation control records that, at a minimum, document the processor's efforts in monitoring and correcting sanitary practices and conditions. The required monitoring information must be recorded at the time it is observed.

I-17. Sanitation Control Records:

"Each processor 'shall' maintain sanitation control records that, at a minimum, document the [sanitary] monitoring and corrections . . . "

21 CFR, Part 123.11(c)

I-18. Sanitation Control Records:

"Processing and other information 'shall' be entered on records at the time that it is observed."

21 CFR, Part 123.9(a) (4)

When sanitation problems are detected as a result of sanitation monitoring, corrections must be taken in a timely manner to ensure compliance with the GMP. Sanitation monitoring and corrections must be documented. These records can be reviewed by inspectors, but are not required to be reviewed by plant personnel. This is in contrast with HACCP records which must be reviewed by plant personnel. Likewise, CCP are subject to mandatory verifications, whereas sanitation controls are not. Although not required by the HACCP rule, reviews and verifications are strongly encouraged in order to support the sanitation control procedures.

I-19. Sanitation Corrections:

"Processors 'shall' correct in a timely manner, those [sanitary] conditions and practices that are not met."

21 CFR, Part 123.11(b) (8)

I-20. **Sanitation Control and Correction Records, must include:**

1. Name and location of the processor;
2. Date and time of the activity recorded; and
3. Signature or initials of the person performing the monitoring operation.

21 CFR, Part 123.9(a)

All sanitation monitoring and corrections, and HACCP records 'shall' be available for official review and copying at reasonable times. Likewise, the sanitation control records shall be retained at the processing facility for at least one year after the date they were prepared in the case of refrigerated products and for at least two years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

I-21. **Sanitation Control Records retained-**

. . . at least 1 year for refrigerated products, and

. . . at least 2 years for frozen, preserved or shelf-stable products

21 CFR, Part 123.9(b)

Sanitation Monitoring

There is no mandatory or specified method or form for routine use in sanitation monitoring. HACCP does, however, require processors to consider all of the eight key sanitation conditions specified in the regulation (I-16). A daily clipboard check sheet is one common approach offered by this course. Other approaches can involve automated recording, electronic records, or other innovative approaches. Monitoring should be customized for the particular processing facility and operation. The success of the monitoring method does not depend on the approach, but on the evidence it yields to reflect routine and appropriate sanitation practices.

The parts that are common to most sanitation monitoring forms are: 1) a specific sanitation condition or practice that is to be monitored; 2) space to record observations or measurements of the condition being monitored at the prescribed frequency for monitoring; and 3) space to document any necessary corrections.

I-22. Common Features for Sanitation Monitoring Forms:

1. Specific sanitation conditions or practices to be monitored;
2. Space to record observations and measurements at the prescribed frequency; and
3. Space to document any necessary corrections.

In most cases, the records can be marks for "Satisfactory" or "Unsatisfactory" (S/U), "Pass" or "Fail" (P/F), "Yes" or "No" (Y/N), or and to denote the sanitary condition or practice. However, more detail is necessary to record 'actual values' or measurements when necessary (e.g., sanitizer concentrations, time of observations, etc.).

The following monitoring forms are provided as examples that could be used in different processing situations (I-23 through I-27). A daily sanitation record form (I-23) taken from the Seafood HACCP Alliance 'Encore' HACCP course is provided to illustrate a variety of considerations in designing a monitoring record. This form addresses both raw (line 1) and ready-to-eat (line 2) seafoods. Note, that for some areas of sanitation the frequency for monitoring is more often for the ready-to-eat line. This form distinguishes a "Pre-Op" inspection from an inspection preformed at the actual "Start" time, while encouraging certain checks at 4-hour intervals or after operations are completed ("Post-Op"). Actual values are recorded for observation times and sanitizer concentrations. Likewise, the monthly sanitation monitoring form (I-24) taken from the "Encore" course can accompany the daily forms. These forms will be used in the following chapters to progressively complete an example sanitation control record.

In contrast, Forms I-25 and I-26 provide a multi-day log that details monitoring of specific areas of sanitation in a processing plant. In most processing operations all of the eight key sanitation conditions are relevant. In some instances, usually for operations with limited processing and handling steps (i.e., warehouses), some of the key sanitation conditions may not be applicable. Form I-27 is an example of a simple daily sanitation record to reflect the character and limited operations associated with warehousing frozen seafoods which involve no manufacturing or reprocessing.

I-23.

DAILY SANITATION CONTROL RECORD

Report Date:_____ Firm Name:_____

Line 1: Raw Seafood (not ready-to-eat)
Line 2: Ready-to-eat

Firm Address:_____

Sanitation Area and Goal	Pre-Op Time:	Start Time:	4 Hour Time:	8 Hour Time:	Post-Op Time:	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hose (S/U)						
2) Condition and Cleanliness of Food Contact Surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U) Line 2: (S/U) ◆ Sanitizer Strength Sanitizer Type:_____ Strength:_____ ppm Line 1: (ppm) Line 2: (ppm) ◆ Gloves and aprons clean and in good repair Line 1: (S/U) Line 2: (S/U)						
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U) ◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U) ◆ Unpackaged cooked products separated from raw products (S/U)						

S = Satisfactory / U = Unsatisfactory

I-23. Continued (page 2)

Daily Sanitation Control Record (page 2)

Sanitation Area and Goal	Pre-Op Time:	Start Time:	4 Hour Time:	8 Hour Time:	Post-Op Time:	Comments and Corrections
4) Maintenance of Hand-washing, Hand-sanitizing, and Toilet Facilities ◆ Hand-washing and hand-sanitizing stations adequate • Hand-washing station Line 1: (S/U) ☐ Line 2: (S/U) ☐ • Hand-sanitizing station Sanitizer Type_____ Strength:_____ ppm Line 2: (ppm) ☐ ☐ ☐ ◆ Toilets clean, properly functioning, and adequately supplied (S/U) ☐						
5) Protection from Adulterants and 6) Labeling, Storage, and Use of Toxic Compounds ◆ Product protected from contamination (S/U) ☐ ☐ ☐ ◆ Cleaning compounds, lubricants, and pesticides labeled and stored properly (S/U) ☐						
7) Employee Health Conditions ◆ Employees do not show signs of medical problems (S/U) ☐						
8) Exclusion of Pests ◆ Pests excluded from processing area (S/U) ☐						

S = Satisfactory / U = Unsatisfactory

Signature or initials _____ Date_____

I-24.

Monthly Sanitation Control Record

Report Date:_____ Firm Name:_____

Firm Address:_____

Sanitation Area	Decision	Comments/ Corrections
1) Safety of Water ◆ Safe and sanitary source (S/U) (annual) ◆ No cross-connections in hard plumbing (S/U)	☐ ☐	
2) Condition and Cleanliness of Food Contact Surfaces ◆ Processing equipment and utensils in suitable condition (S/U)	☐	
3) Prevention of Cross-contamination ◆ Physical conditions of plant and layout equipment (S/U)	☐	

S = Satisfactory / U = Unsatisfactory

Additional Comments:

Signature or initials _____

I-25. Daily Sanitation Control Record for a specific location in the processing plant.

DAILY SANITATION CONTROL RECORD

ABC Shrimp Company
Anywhere, USA

Maintenance of Toilet Facilities **Men's Locker Room**

Date	Time of Check	Cleanliness of Area (1) (P/F)	Facilities Functioning Properly (2) (P/F)	Facilities Adequately Supplied (3) (P/F)	Comments/ Corrections	Check by:
3/22/99	5:50 am	P	P	P		Mr. A
3/23/99	5:35 am	P	P	P		Mr. A
3/24/99	5:55 am	P	P	F	No soap in dispenser; filled with soap	Mr. A
3/25/99	6:03 am	P	F	P	Drain on left sink clogged; turned off water to sink to prevent use; called maintenance	Mr. A
3/25/99	10:15 am	P	P	P	Drain on left sink unclogged	Mr. A
3/26/99	5:48 am	P	P	P		Mr. A

P = Pass / F = Fail
(1) Cleanliness of sinks, floors, stalls, trash removed.
(2) Hot water available, drains functioning, toilets functioning.
(3) Soap, paper towels, and toilet paper provided.

I-26. Monitoring for a specific location in the plant.

SANITATION CONTROL RECORD

Any Seafood Company
Anywhere, USA

Condition of Chemical Storage Area

Date	Time of Check	Storage Area Secure? (Y/N)	Chemical Containers Closed? (Y/N)	Chemicals Properly Labeled? (Y/N)	Clear of Chemical Spillage? (Y/N)	Comments/ Corrections	Check by:
3/22/99	8:05 am	Y	Y	Y	Y		SAM
3/23/99	8:10 am	N	Y	Y	Y	Gate unlocked: locked gate: notified sanitation supervisor	SAM
3/24/99	7:58 am	Y	Y	Y	Y		SAM
3/25/99	8:03 am	Y	N	Y	Y	Lid off drain of de-icer compound: replace lid and labeled: notified sanitation supervisor	SAM
3/26/99	7:50 am	Y	Y	Y	N	Sanitizer dripping from board: tighten valve: cleaned up spill	SAM

Y = Yes; N = No

I-27. Daily Sanitation Control Record for a frozen seafood warehouse operation

DAILY SANITATION RECORD

Name: *Any Frozen Seafood Storage Warehouse* Report Date & Time: *4/1/99 8am*

Address: *Anywhere*

Sanitation Condition *Metropolis, USA*	✘ Or ✓ Completed By: *BSJ*	Comments and Corrections
Receiving and staging areas cleaned and sanitized.*	✓	
Raw products and cooked products stored in designated areas or are covered to prevent cross contamination in refrigerated storage.*	✓	
Toilets and hand washing sinks are clean, adequately supplied, and functioning properly.*	✘	*Broken toilet lid; replaced with new lid.*
Cleaning compounds, lubricants and pesticides are properly labeled and stored.	✓	
Employees do not show signs of medical problems. *	✓	
Pests excluded from product storage area.	✘	*Droppings from rodents in dry storage area; cleaned area and re-baited.*

✓ = Pass
✘ = Fail

* These items may not be applicable in all situations, particularly those where the product is not exposed.

References

For additional information on sanitation procedures, regulations and HACCP:

Food Code, 1999. FDA, U.S. Public Health Service, 431 p.tt. Available -- National Tech. Information Service, phone 1-800-553-6847 or fax 703-605-6000 or e-mail <orders @ ntis.fedworld.gov>. Request book PB99-115925KOU for $40 or CD-ROM, PB99-500506KOU for $69; or diskette, PB99501033KOU for $69. Also, view or download from website -- http://vm.cfsan.fda.gov/~dms/fc99.toc.html Request book PB99-115925KOU for $40 or CD-ROM, PB99-500506KOU for $69; or diskette, PB99501033KOU for $69. Also, view or download from website -- http://vm.cfsan.fda.gov/~dms/fc99.toc.html

HACCP: Hazard Analysis and Critical Control Point Training Curriculum, Third Edition (English) July 1996, 276 pages, and Second Edition, 1997 (Spanish), UNC-SG-98-07. Manual available bound - North Carolina Sea Grant, Box 8605, NC State University, Raleigh, NC 27695-8605 or call 919/515-2454.

HACCP Alliance website information:
http://seafood.ucdavis.edu/haccp/ha.htm

Chapter 1
Safety of Water

Introduction

This chapter relates to the source and transport of water that comes into contact with food or food contact surfaces or is used in the manufacture of ice. Cross-connections between potable and non-potable water systems are also discussed.

A primary safety concern for any food processing operation should be the safety of water. A complete SSOP plan must first account for the sources and treatment of water that comes in contact with food or food contact surfaces or is used to make ice. It must also consider cross-connections between the safe water supply (potable water) and any unsafe or questionable water supply (non-potable) or sewer disposal systems. In seafood processing plants, cross-connections have been found in many places, such as, hard plumbing between potable and non-potable water lines; unprotected hose bibs (i.e., those with no backflow prevention devices); hoses lying in pooled water or submerged in wash tanks; or metering pumps used for cleaning chemicals without a backflow prevention device.

1-1. Key Sanitation Condition No. 1:

- Safe supply for water that contacts food and food contact surfaces;
- Safe water supply for production of ice; and
- No cross-connections between potable and non-potable water.

Water is of major importance because of its broad use and application in food processing. It is used: 1) as an ingredient in some seafood products; 2) to convey or transport products; 3) to wash foods; 4) to clean and sanitize facilities, utensils, containers, and equipment; 5) to make ice and glazed products; and 6) for drinking. All of these require safe water that will not cause contamination of the food.

1-2. Water is one of the most important components of a seafood establishment since it is used:

- As an ingredient;
- To convey or transport products;
- To wash foods;
- To make ice and glazed products;
- To clean and sanitize facilities, utensils, containers and equipment; and
- For drinking.

The current Good Manufacturing Practices (GMP) Regulation (21 CFR Part 110) states that the water supply in a food processing plant shall be sufficient for the operations intended and shall be derived from an adequate source; and any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. In most instances, the "adequate supply . . . of adequate sanitary quality" has been interpreted to mean from a 'potable' water supply based on certain nationally established drinking water standards. An 'approved' source is most often determined by local and state regulatory guidelines. These local guidelines can address water obtained from public or municipal sources, private sources (wells), and coastal waters (seawater). State authorities often reference the "National Primary Drinking Water Standards" established by the U.S. Environmental Protection Agency (EPA). Additional information including the intended uses are considered in evaluating well water and seawater sources.

Monitoring - Sources

Whether water is obtained from a public or municipal source, private well, or as seawater, the supply must be monitored with sufficient frequency to assure that the water is safe for use on foods and food contact surfaces.

1-3. Common sources for water used in seafood processing:

- Municipal;
- Private wells; and
- Seawater.

Municipal Water

If water comes from a municipal source, a copy of the water bill will usually be sufficient documentation for an approved water supply (1-4). This seems simple, and it is. Although it is not required, it may also be helpful to request a copy of the municipality water quality analysis. In addition to water safety information, this analysis may reveal information (e.g., water hardness and mineral content) that could influence processing conditions other than food safety. The water bill and analysis should be obtained annually and filed with a periodic or monthly Sanitation Control Record (Form 1-4). Some firms may choose to perform additional analyses and store the results in their periodic sanitation records.

1-4. Periodic sanitation control record

Monthly Sanitation Control Record

Report Date: 1/21/99

Firm Name: Any Seafood Co., Inc

Firm Address: Anywhere, USA

Sanitation Area	Decision	Comments/ Corrections
1) Safety of Water ◆ Safe and sanitary source (S/U) (annual) ◆ No cross-connections in hard plumbing (S/U)	S U	Municipal water bill and analysis on file (1/10/99) Requested installation of air gap in water line used to fill new thaw tank
2) Condition and Cleanliness of Food Contact Surfaces ◆ Processing equipment and utensils in suitable condition (S/U)		
3) Prevention of Cross-contamination ◆ Physical conditions of plant and layout equipment (S/U)		

S = Satisfactory / U = Unsatisfactory, requires correction

Additional Comments:

Air gap installed 1/22/99

Signature or initials BSJ

Private (Well) Water

Likewise**,** private water sources should be monitored to determine if the water meets approved standards. This requires laboratory analysis, which at a minimum should include testing for indicator bacteria such as total coliforms. For example, well water testing should be conducted before any new source is used for processing operations, then at least on a semi-annual basis or more frequently for suspect sources. The frequency for sampling will usually be specified by the local or state requirements.

1-5. Private water monitoring:

Private water monitoring should be conducted before any new service is used for processing operations and then at least on a semi-annual basis or more frequently for suspect sources in accordance with state requirements.

Seawater

It is reasonable to expect the water safety considerations for use of seawater for processing should at least match the considerations for potable water from municipal and private sources. For this reason, the company or vessel using seawater to process fish and fishery products should consider monitoring the original source, the water after any necessary treatments , and water from storage tanks. Realizing that seawater conditions can change due to seasons and coastal activities, monitoring could be more frequent than for land-based municipal or private sources. Although the water will contain higher amounts of salts than found in freshwater, the saltwater used on food and food contact surfaces must at least meet the safety requirements for drinking water. In situations where it does not, careful consideration must be given to the safety and aesthetic risks associated with its use.

For example, testing may not be needed when seawater is simply used to offload whole fish from vessels using pumps or flumes. However, when seawater is used for processing and comes into direct contant with fillets or the edible parts of other seafood products, seawater sources need to be more carefully monitored. This monitoring could include testing, depending on local conditions (i.e., red tides) and water quality.

1-6. Sea water monitoring:

Monitoring for seawater safety in processing should be conducted more frequently than for land-based municipal or private sources. The guidelines should be in accordance with state requirements and locally approved testing labs.

Monitoring - Plumbing

Monthly monitoring is also usually adequate for problematic cross-connections in hard (permanent) plumbing between the potable water lines and non-potable water or sewer lines. More frequent (e.g., daily) monitoring is required to prevent potential water contamination from cross-connections created by back siphonage or improper use of hoses (e.g., direct submergence in tanks; lying on the floor). Cross-connection problems due to back siphonage should be monitored and recorded before processing (Pre-Op). Any problems should be immediately corrected and so recorded in a Daily Sanitation Control Record (1-7). The most effective remedy for back siphonage or backflow is a simple air gap (space) between the water source and the tank, holding container, or water on the floor. Wherever this is not practical, vacuum breakers of several types are available to prevent backflow. Whenever malfunctioning vacuum breakers are discovered, they must be repaired or replaced immediately and the correction noted in the Daily Sanitation Control Records. In most areas, specific local public health ordinances specify under what conditions and in what manner they must be used.

Monitoring - Ice

In addition to monitoring for the safety of the water source and associated plumbing, periodic monitoring should be conducted for the safety of the ice made from the water supply. Ice and its storage and handling conditions can be responsible for spreading problematic bacteria. This situation usually results from contamination of the ice as a result of insanitary storage, conveying, shoveling, or contact with floors. These sanitary conditions involve indirect food contact surfaces which are discussed in Chapter 2 as part of the required monitoring for the condition and cleanliness of food contact surfaces.

Corrections

When monitoring detects a problem with the processing water source, the processor must evaluate the situation and, if necessary, discontinue use of water from that source until the problem is solved and retesting confirms that it no longer exists. Additionally, the need to take action regarding any and all products produced under the adverse conditions must be assessed.

When monitoring detects cross-connections in the hard plumbing, the problem must be corrected immediately. If the problem portion of the water supply cannot be isolated (e.g., use of a shutoff valve), processing should be discontinued until the repair can be made. Additionally, product processed under the deficient conditions must be withdrawn from distribution until their safety has been established.

When monitoring detects the absence of a vacuum breaker on a hose bib or some other condition that could lead to back siphonage, the condition must be corrected as soon as practical and immediate action must be taken to prevent contamination. All repairs and other corrections must be recorded on the appropriate Daily Sanitation Control Record.

Records

Sanitation control records are necessary to document that the processor is consistently conforming to sanitary conditions and practices. The actual records will vary to accommodate differences in processing operations. The example provided at 1-4 is a Periodic Sanitation Control Record completed on 1/21/99. The processor chose to attach a copy of that month's municipal water bill and a copy of

the municipal water supplier's water analysis to the record. The processor noted on the record that the attached bill and analysis were filed. This is ample documentation of the adequacy of the water source. If a private water source or seawater were used in the operations, the results of the water testing would also be recorded on this form. Test results should be recorded and stored. If any contamination is indicated, corrections and retesting results should be recorded and stored with the appropriate Sanitation Control Record.

The record also includes a check mark indicating that the processor had performed a monthly check for the presence of cross-connections in the hard plumbing. In addition, the Daily Sanitation Control Record provided at 1-7 includes the daily pre-op check for potential back siphonage conditions, especially those related to hoses.

Note, records for the sanitary conditions for ice, ice storage, and ice handling would be according to the daily monitoring for food contact surfaces (Chapter 2).

I-7.

DAILY SANITATION CONTROL RECORD

Report Date: 10/22/99

Firm Name: Any Seafood Co., Inc.

Firm Address: Anywhere, USA

Line 1: Raw Seafood (not ready-to-eat)
Line 2: Ready-to-eat

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time:	4 Hour Time:	8 Hour Time:	Post-Op Time:	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hoses (S/U)	U					Replaced backflow preventor on hose faucet #3
2) Condition and Cleanliness of Food Contact Surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U) Line 2: (S/U) ◆ Sanitizer Strength Sanitizer Type:_____ Strength:_____ ppm Line 1: (ppm) Line 2: (ppm) ◆ Gloves and aprons clean and in good repair Line 1: (S/U) Line 2: (S/U)						
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U) ◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U) ◆ Unpackaged cooked products separated from raw products (S/U)						

S = Satisfactory / U = Unsatisfactory

Background

Water Standards

The National Primary Drinking Water Regulations established by the U.S. Environmental Protection Agency are legally enforceable standards that apply to public water systems. They are developed to protect public health. These standards are commonly referenced by state and local authorities in establishing regulatory guidelines and requirements for all water supplies or sources, both fresh or salt, used in food processing. They contain limits or maximum contaminants levels (MCL) for numerous organic and inorganic chemicals (e.g., lead, mercury; dioxin and PCBs). Likewise, they list the MCL for certain microorganisms. The most notable and commonly used microbial limit is for total coliforms, including fecal coliform and *E. coli*. These bacteria are used as a measure or indicator for other potentially harmful bacteria that may be present. They are a common indicator for potential water contamination from human or animal fecal waste.

1-8. EPA National Drinking Water Regulations for Microorganisms

	MCL Goal	MCL*
Total coliforms (including fecal coliforms & *E. coli*)	zero	5%**
viruses (enteric)	zero	99.99% killed or inactivated
Giardia lamblia	zero	99.99% killed or inactivated

*MCL - Maximum Contamination Level

**No more than 5.0% of the water samples total coliform-positive in a month. Every sample that has total coliforms must be analyzed for fecal coliforms. The presence of any fecal coliforms is unacceptable in drinking water.

Total coliforms can be found in the water environment and are generally not harmful. However, water treatment is necessary to remove coliforms from water used for drinking or direct food contact. The presence of these bacteria in drinking water is generally a result of a problem with water treatment or the pipes that distribute the water, and indicates that the water may be contaminated with harmful organisms. Total coliforms are not only a useful indicator of potential sewage contamination, but are also a useful screen for the actual presence of problematic coliforms like *E. coli*. The presence of *E. coli* is strong evidence that fresh sewage is present in the water.

Total coliforms are not a perfect indicator of the actual or potential presence of harmful organisms. Some disease-producing organisms, especially the protozoa such as *Giardia* and *Cryptosporidium*, are able to withstand treatments that remove total coliforms. These two protozoa can be found in surface waters contaminated by human sewage or wildlife. The principal viruses that cause problems in water (i.e., hepatitis A and Norwalk agent) can be associated with fecal contamination. Chlorination normally inactivates these viruses.

Water Sources

Municipalities are the most common source of water for processing fish and fishery products. It is often the more expensive source, but cost must be weighed against safety, quality and availability. Municipal water typically maintains high quality standards for both chemical and microbiological content; it usually has been purified or treated; and it is tested on a pre-determined schedule.

1-9. Most common water source obtained from municipalities have:

- ◆ High chemical and microbiological standards;
- ◆ Been purified or treated; and
- ◆ Been tested on a pre-determined schedule.

Private water can come from a variety of surface sources, but it is most often obtained from wells. Wells are drilled by food plants to provide less costly, more reliable, or higher quality water than might be available locally. Properly maintained, wells can provide clean water that assures high quality and food safety, but they are often more subject to contamination than most municipal sources. Well water may contain a higher amount of dissolved minerals, undissolved solids, organic matter, dissolved gases, and microorganisms than municipal water. Chemical and microbiological contamination of well water can occur from a variety of sources. Sewage can enter wells if they are flooded or are located too close to cesspools, septic tanks, or associated drainage fields. Well casings or linings that are cracked or improperly sealed may leak and allow contamination. Floods or heavy rains, which occur frequently in coastal areas where seafood processing facilities are commonly located, also can allow surface water to enter the well and produce contamination. Similarly, surface debris can enter wells unless adequate protection is provided. One other source of contamination is the ground water itself, which may enter the well without sufficient natural filtration and percolation to remove impurities. Chemical pollution of wells has occurred through leaking fuel tanks; the application of agricultural chemicals on farms, home gardens, and golf courses; and industrial discharges.

Well water may or may not be less contaminated than water from other sources. The decision on whether or not to add disinfecting chemicals must be based on microbiological tests which can be performed by either local health agencies or private laboratories. In many cases, local public health authorities can also provide information on the proper and legal construction of wells. For example, Virginia authorities recommend; that the well head should be located about 2-3 feet above the surface and the ground sloped away from the casing to prevent entry of surface water; sources of sewage and landfills should be at least 200 feet distant, depending on the soil condition and rate of water movement through it; well casings should be welded or threaded to prevent entry of surface water and they should be sealed to a concrete curb at least 24 inches high in order to prevent contamination from surface water; a screened or filtered vent must be provided to prevent a vacuum from forming within the well that could draw in contamination; and water should never be drawn from a level of less than 10 feet below the surface.

1-10. Chemical and microbiological contamination of well water can occur due to:

- Flood or heavy rains;
- Location too close to cesspools, septic tanks, agricultural sites, or associated drainage fields; or
- Cracked or improperly sealed well casings or liners.

The use of **seawater** in processing is usually limited to some remote coastal locations and certain processing vessels. In some situations it has been drawn from local, active harbors. As a natural source subject to daily and seasonal conditions, and environmental contamination, the safety and quality of the water may be questionable. In these situations, treatment, such as chlorination or restricted uses may be sufficient to eliminate microbial concerns. For example, use can be restricted to primary processing steps that do not influence food safety (e.g., fluming whole fish), to be followed by further processing and wash steps with a potable water supplied from a reservoir or storage tank. Because salt and corrosion can also influence product quality, flavor and appearance, their influence must also be considered when determining the use of seawater in processing operations.

In addition, when operating in an area where there is a visible oily sheen on the water, or where oil can be seen on the beaches adjacent to the water a processor, or operator of a fish processing vessel should **not** take on sea water for (1) fluming, pumping, unloading, or chilling seafood; (2) holding live seafood products, or; (3) cleanup purposes. The intakes for the seawater tanks on processing vessels should be located near the bow whenever possible, and on the opposite side of the keel from any domestic and processing waste discharge points. Vessels, at anchor, should swing from a bow anchor to minimize the possibility of pulling contaminated water into the seawater intake system.

Seawater used in contact with foods and food contact surface should meet similar potable water guidelines required for municipal and private water sources. The World Health Organization (WHO) defines 'clean sea water' as seawater which meets the same microbiological standards as potable water and is free from objectionable substances. Potable water is defined by the drinking water standards established by EPA.

1-11. World Health Organization's recommendations:

(WHO) defines 'clean sea water' as seawater which meets the same microbiological standards as potable water and is free from objectionable substances.

In accordance with the previously stated requirements for potable water, seawater would be subject to monitoring and possible treatment to remove microorganisms before use in processing operations. In addition to concerns for bacterial contaminants, natural seawater may also contain chemical

pollutants from coastal or ship activity, and natural toxins (e.g., red tides). For these reasons, the monitoring for seawater safety should be more extensive and frequent than used for land-based sources.

According to potable water requirements of the Vessel Sanitation Program developed for passenger ships by the Centers for Disease Control (CDC), water monitoring on these vessels should also include frequent measures for treatment with free halogen residuals (e.g., chlorine content). These guidelines would apply to all vessel water, fresh or salt, used for contact with food and food contact surfaces.

1-12. Passenger Vessel Sanitation Program Guidelines for Potable Water Use

Source:	Potable according to EPA's National Primary Drinking Water Regulations
Treatment:	Halogen level (e.g., free chlorine content) greater than 0.2 mg/liter (ppm) and less than 5.0 ppm.
Monitoring:	Minimum of four samples per month to assure zero *E. coli.*
Storage:	Tanks do not share common walls with the vessel hull or with tanks containing non-potable water or other liquids; interior tank coatings approved for potable water contact (non-corrosive); tank vents and overflows protected from contamination; and device used to check tank water depth will not contaminate.
Piping:	Must be colored (blue) and labeled for potable water use; no potable water piping to pass under or through sewage or other tanks holding non-potable liquids; no non-potable piping passing through or under tanks holding potable water.
Hoses:	Colored and labeled for potable water use only; unique hose fillings from all other hose fittings, flush before use and drain after use.

Source: Vessel Sanitation Program Operations Manual, 1999.
Centers for Disease Control and Prevention - VSP, Atlanta, GA

In-Plant Water Contamination

Caution must be exercised to avoid contamination of the potable water system with fluids from other sources. This type of contamination may occur as a result of cross-connections, backflow, or back siphonage. These problems can result from improper installations, altered plumbing and additions to the existing plumbing. Also, submerged inlets can result from the improper placement of unrestricted pipe intakes or open hoses. In some cases, the problems may result because the plumber doing the installation or modification was unaware of the potential water quality problems.

1-13. Causes of In-Plant Water Contamination

- ◆ Cross-Connections
- ◆ Backflow
  - back pressure
  - back siphonage

Cross-connections occur when the plumbing allows potable water to mix with any non-potable water, particularly sewage, or other liquids. The cross-connection can be a direct link between the sources or an indirect link whereby the contaminating source is sucked or forced into the potable source. Examples of indirect links include faucets positioned below toilet bowls or wash tanks, and submerged inlets. According to plumbing guidelines, a submerged inlet is any unrestricted connection to a fixture (e.g., pipe or hose) with an opening positioned less than two diameters above the highest level possible for the potable water or potential contaminating liquid. For example, an open hose submerged in a tank of water.

Backflow problems occur when pressure differences in the water distribution system forces contaminants into the potable water supply. It can result as 'back pressure' pushing contaminants into the potable supply or 'back siphonage' when the pressure in the potable water supply is less (negative pressure) than atmospheric pressure. Differences in pipe sizes, water flow rates, and water levels create these problems.

Usually a well-designed and properly maintained air gap is the best means available to protect against backflow problems. Plumbing guidelines recommend air gaps twice the effective opening of the potable water outlet diameter and the gap should be at least one inch. For example, most local authorities require air breaks on water lines inside toilet tanks.

When air gaps are not possible, vacuum breakers can be used to allow atmospheric pressure to enter the piping system to eliminate any vacuum pulling liquids into the potable supply. Vacuum breakers come in two types; pressure and non-pressure. A qualified plumber should be aware of the proper selection and placement depending on the pipe/faucet configurations and water use. Monitoring and qualified checks or installation should become part of a periodic sanitation control record.

1-14. Backpressure can be a source of contamination when

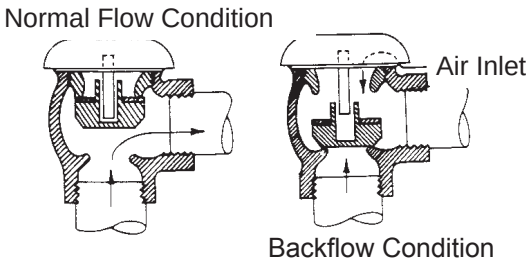
- ◆ A potable water system is connected to a system operating under a higher pressure by means of a pump, boiler, elevation difference, or air or steam pressure.

One other potential source of water contamination in the food environment deserves mention: water softening or deionizing devices. Often this source of contamination is first suspected when water has an off-odor or flavor. Total plate counts will be extremely high, and in fact, the water may even be turbid (cloudy) as a result of the high numbers of bacteria that it contains. Despite this condition, tests for total coliforms will usually be negative. Although the microorganisms that are likely to grow in deionizers are nonpathogenic, their presence is undesirable, and every effort should be made to prevent their growth. Frequent back flushing of the resin bed, and periodic resin bed replacement is the most satisfactory means of controlling contamination.

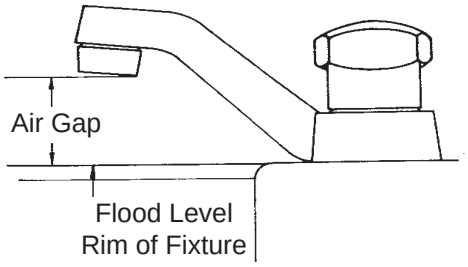
1-15. Backflow control:

- Air gap
- Vacuum breaker
- Check valve

Atmospheric Vacuum Breaker

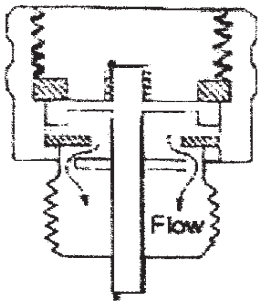


Air Gap and Effective Opening

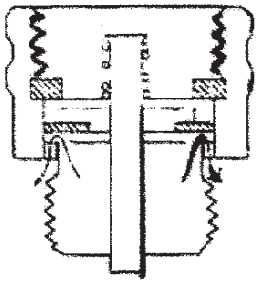


Operation of a Hose Connection Vacuum Breaker

(A) Open Position



(B) Closed Position



Vent to Atmosphere

1-16.

Sanitation Control Guide

Entry date:	Water Quality	FDA Key Condition No. 1

Concern: Safety of Processing Water and Ice

Examples:
Municipal water supply suspect or not routinely checked. Well water supply suspect or not routinely checked.

Controls and Monitoring:

Obtain copies of municipal water bills and document their verification procedures. **Frequency: Before initiating business, then one monthly billing as annual evidence of service.**

For well water conduct water tests for total coliforms and/or other attributes prescribed by local authorities. **Frequency: Before initiating business, then semi-annual or as advised by local authorities.**

(Note: Quality of ice used in contact with seafoods depends on the quality of the water and the cleanliness and condition of the ice storage area which is monitored as a contact surface in FDA Key Condition No. 2.)

Recommended Corrections:
Maintain file of municipal water bills. Stop use of any contaminated water until properly treated and retested.

Records:
Monthly & Semi-Annual Sanitation Control Records

1-17.

Sanitation Control Guide		
Entry date:	Cross-Connections in Hard Plumbing and Back siphonage-hoses	FDA Key Condition No. 1

Concern: Safety of Processing Water and Ice

Examples:
Improper plumbing connections could allow mixing of potable water and waste water. Hoses and faucets on water outlets are submersed in tanks, flumes, or hoppers used to hold, move, thaw or wash product during processing.

Controls and Monitoring:

Check plumbing installations, flow patterns and conditions to determine any potential problems with cross-connections or backflows. **Frequency: Immediately following new installation or changes, and semi-annually.**

Check plumbing installations and all water outlets to provide air gaps or backflow prevention devices. **Frequency: Immediately after new installations and changes, daily pre-ops, and semiannual for entire plant operations.**

Recommended Corrections:
Immediately correct any cross-connections and determine any potential contamination of product that may need to be reprocessed, recalled or destroyed. Install proper air gaps and backflow prevention devices.

Records:
Daily Sanitation Control Records for installations, changes and pre-ops
Monthly Sanitation Control Records for semiannual checks

References

American Water Works Association. 1990. Recommended Practice for Backflow Prevention and Cross-Connection Control. AWWA Manual M14a-92. Second Edition. Denver, CO. 124 pp.

Chapter 2

Condition and Cleanliness of Food Contact Surfaces

Introduction

This chapter relates to the design, workmanship, materials, and maintenance of food contact surfaces and the routine, scheduled cleaning and sanitizing of those surfaces, including gloves and outer garments.

2-1. Key Sanitation Condition No. 2:

Condition and cleanliness of food contact surfaces

Food contact surfaces in food processing can include all equipment, utensils and facilities used during processing; as well as, worker clothing and hands, and packaging materials. This is a very comprehensive concern because potential food contamination can come from numerous direct or indirect routes that are not always obvious during the processing operation.

2-2. Food Contact Surface:

"Those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations" (GMP, 21 CFR 110.3). Typical food contact surfaces include utensils, knives, tables, cutting boards, conveyor belts, ice makers, ice storage bins, gloves, aprons, etc."

Monitoring

2-3. Goal:

Monitoring should provide assurance that food contact surfaces including gloves and outer garments are properly designed, constructed and maintained to facilitate sanitation, and that they are adequately and routinely cleaned and sanitized.

A complete SSOP plan will account for all food contact surfaces that could lead to direct or indirect contamination of foods during processing. A monitoring program should ensure that, 1) processing equipment and utensils (food contact surfaces) are in suitable condition for sanitary processing, 2) equipment and utensils are properly cleaned and sanitized, 3) the type and concentration of sanitizer(s) is acceptable as applied, and 4) that gloves and outer garments which might contact food are clean and in good condition.

2-4. What to Monitor:

- Condition of the food contact surfaces;
- Cleanliness and sanitation of food contact surfaces;
- Type and concentration of sanitizer(s) used; and
- Gloves and outer garments which might contact food are clean and in good condition.

At its simplest, the monitoring of food contact surfaces typically involves a combination of visual checks and chemical testing of sanitizers. Visual inspection includes confirmation that surfaces are in good condition so that they can be properly cleaned and sanitized. Also, gloves and outer garments must be clean and in good repair. Monitoring includes visual checks for the construction and condition of surfaces. Proper lighting and polished or light-colored surfaces allow for easier detection of residues on surfaces. Some pieces of equipment may require disassembly to identify areas which trap food particles. The monitoring process looks for recesses, poorly bonded joints, corroded parts, exposed bolts or screw heads or other areas which trap water or soils which could hinder the effectiveness of cleaning and sanitation procedures.

Chemical testing is very simple for most commonly used sanitizers, such as chlorine, iodine, and quaternary ammonium compounds. Special test strips change color in the presence of a specific sanitizer, and the intensity of color indicates chemical concentration. The strips quickly provide results that are sufficient for most tests. Instructions accompanying the strips explain the proper use since some instantly change color while others must be soaked for a certain period of time. Although accurate, most test strips allow for determining a concentration range, not a precise concentration. Also, test strips are not available for all sanitizers. Colorimetric test kits requiring simple chemical mixing are available for many sanitizers. Most are precise, relatively rapid and require little training. Chemical or laboratory suppliers to the food industry can usually furnish test strips and kits.

Periodic verification checks for sanitation, such as microbiological testing of surfaces, is recommended but is not required. These methods are described later in this chapter.

2-5. How to Monitor:

◆ Visual Inspection --

- Surfaces in good condition;
- Surfaces cleaned and sanitized; and
- Gloves and outer garments clean and in good repair.

◆ Chemical Testing --

- Sanitizer concentration (test strips or kits).

◆ Verification Checks --

- Microbial tests of surfaces (optional).

Monitoring frequency depends on what is monitored. Inspection of equipment for proper design (ensuring adequate drainage, for example) and evidence of corrosion may be sufficiently performed on a monthly schedule. Sanitizer concentrations are usually determined at the time they are applied as part of plant clean-up procedures. Where sanitizers are prepared over the course of the day, they should be checked periodically during the day. The frequency of the checks should be determined by the conditions of use. Certain sanitizers degrade more quickly than others and require more frequent monitoring before application to surfaces. Typical monitoring schedules are shown in the example monitoring record 2-8 and later in the Sanitation Control Guides. In addition, the adequacy of equipment cleaning should be verified after each cleaning and sanitizing operation.

Corrections

Problems discovered during monitoring must be corrected in a timely manner. If a piece of equipment is corroded, the correction may involve refinishing or replacement of the equipment. If a work surface is not cleaned it should be properly cleaned and sanitized before beginning work. If a sanitizer concentration is too weak, it should be replaced or adjusted to the proper strength. This implies that targets (criteria) must be established to identify whether conditions are acceptable or unacceptable. For example, chlorine sanitizers are usually applied to food contact surfaces at approximately 100-200 ppm available chlorine. If monitoring indicates a concentration outside of this range, the concentration must be corrected and documented. The background section of this chapter provides details that should help in establishing acceptable ‘targets.’

2-6. Typical Corrections:

- Observation: Sanitizer concentration from dispenser varies day to day.
  Correction: Repair or replace chemical proportioning equipment and train cleaning crew in its proper use.

- Observation: Juncture of two table tops traps food debris.
  Correction: Separate tables to allow access for cleaning.

- Observation: Table work surfaces show signs of corrosion.
  Correction: Refinish or replace damaged equipment and switch to less corrosive cleaning compound.

Records

Sanitation control records provide evidence that the company's sanitation program is adequate, that it is followed and problems are identified and corrected. The actual records or recording forms will differ to suit a particular processing operation. The example records (2-7 and 2-8) identify monthly and daily check points in one of numerous possible formats for recording observations. Notice some of the approaches used in the various types of records.

- The Monthly Sanitation Control Record (2-7) allows for a more comprehensive check of the conditions and workmanship of all food contact surfaces and equipment in the plant, while the corresponding Daily Sanitation Control Record (2-8) can allow for more detailed checks for the cleanliness of the food contact surfaces.

- Observations (S/U in 2-8) are recorded more frequently for those food contact surfaces associated with ready-to-eat products than those associated with the raw, to-be-cooked seafood processing line.

- A pre-operational monitoring (Pre-Op) check (2-8) is recommended for all processing operations. It discovers any problems and makes necessary corrections before any processing begins.

- Pre-Op and "Start" conditions can differ. For example, in 2-8, a Pre-Op check monitors cleanliness of the equipment, while another check at "Start" is necessary to assure that the workers have clean gloves and aprons, something that can not be checked during pre-op.

- Actual values are recorded where a value is available such as sanitizer concentrations, etc. The type and strength of the sanitizer being used is listed as a useful reminder of the target value.

- Ample space is available to mark corrections. An "Unsatisfactory" (U), observation is always followed by a recorded correction.
- The times for all observations, including corrections, are recorded.

2-7.

Monthly Sanitation Control Record

Report Date: 1/21/99

Firm Name: Any Seafood Co., Inc

Firm Address: Anywhere, USA

Sanitation Area	Decision	Comments/ Corrections
1) Safety of Water ◆ Safe and sanitary source (S/U) (annual) ◆ No cross-connections in hard plumbing (S/U)	S U	Municipal water bill and analysis on file (1/10/99) Requested installation of air gap in water line used to fill new thaw tank
2) Condition and Cleanliness of Food Contact Surfaces ◆ Processing equipment and utensils in suitable condition (S/U)	U	Replaced cracked cutting board at station no. 2
3) Prevention of Cross-contamination ◆ Physical conditions of plant and layout equipment (S/U)		

S = Satisfactory / U = Unsatisfactory

Additional Comments:

Air gap installed 1/22/99

Need plan to phase out all wooden cutting boards

Signature or initials BSJ

2-8.

Daily Sanitation Control Record

Report Date: 10/22/99

Firm Name: Any Seafood Co., Inc.

Line 1: Raw Seafood (not ready-to-eat)
Line 2: Ready-to-eat

Firm Address: Anywhere, USA

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time:	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hoses (S/U)	U					Replaced backflow preventor on hose faucet #3
2) Condition and Cleanliness of Food Contact surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U)	S					
Line 2: (S/U)	S		S	S		
◆ Sanitizer Strength Sanitizer Type: Chlorine Strength: 100-200 ppm Line 1: (ppm)	100					Adjusted to 100 ppm before use (4:40P)
Line 2: (ppm)	100		100	50		
◆ Gloves and aprons clean and in good repair Line 1: (S/U)		U				Replaced 10 pairs of gloves (8:30A)
Line 2: (S/U)		S				
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U)						
◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U)						
◆ Unpackaged cooked products separated from raw products (S/U)						

S = Satisfactory / U = Unsatisfactory

Background

Materials for Food Contact Surfaces

Proper selection of materials and design of food contact surfaces can help prevent potential food contamination. Features for durability and function are important, but they cannot compromise concerns for food safety. In simple terms, surfaces should be safe, non-corrosive and easily cleaned and sanitized.

2-9. General Requirements for Food Contact Surface

- Safe Material --
  - Non-toxic (no leaching of chemicals);
  - Non-absorbent (can be drained and/or dried);
  - Resist corrosion; and
  - Inert to cleaning and sanitizing chemicals.
- Fabrication --
  - Can be adequately cleaned and sanitized; and
  - Smooth surfaces including seams, corners, and edges.

A complete discussion of all the various food contact materials is beyond the scope of this chapter, but the following points should be considered.

Most metal surfaces are prone to corrosion directly from the foods (e.g., pickled seafood, brines or marinades) or from chemicals used in cleaning and sanitizing. Selection of metal surfaces must consider the process and food type. The corrosion process occurs due to acidity (pH), salinity, temperature, and time of exposure. Joining two or more dissimilar metals will often greatly accelerate corrosion due to the generation of a small but destructive electric voltage between the pieces.

Stainless steel is often the preferred food contact surface because it can be fabricated with a smooth cleanable finish and it is durable. Although the initial investment can be relatively high, the cost can be recovered through reduced maintenance and prolonged use. Stainless-steel materials in the 300 series (grades) are typically used in food processing. Grained stainless steel can be very attractive, but these surfaces contain thousands of tiny grooves in the surface, making cleaning difficult. These should not be used.

2-10. General characteristics of some food contact surfaces

Surface Materials	Concerns	Recommendations
Black Iron or Cast Iron	Acids or chlorinated detergents. Can cause rust. Lacks strength.	Not recommended in food processing.
Concrete	Often etched by acidic seafoods and cleaning compounds. Can crack.	Concrete should be dense and acid resistant. Materials should not loosen from surface. Use alkaline cleaners.
Glass	Strong caustic cleaning compounds can etch.	Clean with moderately alkaline or neutral detergents.
Plastics	Some stain easily. Currently available materials cannot be used at very low or high processing temperatures.	Best to color coordinate items for intended use (i.e., raw vs. cooked) and select plastics that will not deform or crack when exposed to processing temperatures.
Rubber	Damaged by certain solvents. Trimming boards can warp and their surface can dull knife blades.	Avoid porous or spongy types that hold water or food debris.
Stainless Steel	Expensive, certain grades are pitted by chlorine or other oxidizers.	Best metal surfaces for food processing. Consider 300 level series.
Lead	Solder and flux containing lead in excess of 0.2% may not be used as a food contact surface	Try to eliminate use in food processing plant.
Wood	Pervious to moisture and oils/fats. Softened by alkali and other caustics. Often difficult to clean.	Treated woods must meet criteria for wood preservatives as defined in 21 CFR 178.380. Limit use as food contact surface.
Galvanized metals	Tend to rust leaving a white powder by-product due to zinc corrosion that could cause product adulteration.	Avoid use as food contact surface. Should not be used with acidic foods.
Paint and sealants	Chemical leaching, flaking, and peeling.	Generally not recommended for direct contact surfaces, especially those subject to abrasion. Use only approved substances.

2-11. Food conditions that can influence choice of appropriate food contact surfaces

Pickled fish *(e.g., herrings, mackerel)*	Strongly corrosive; High acidity and salts
Salt cured fish products *(e.g., smoked fish, brined shrimp)*	Moderately corrosive; Medium acidity and salts
Fresh and refrigerated fish *(e.g., peeled shrimp, fillets, shucked oysters, picked crab meat, surimi)*	Weakly corrosive, Low acidity
Fish powders, Dried fish *(e.g., freeze dried shrimp, fish protein concentrate)*	Non-corrosive
Frozen Fish *(e.g., IQF frozen shrimp)*	Non-corrosive

Aluminum is used primarily for construction of utensils because of its low density as well as low fabrication costs. Aluminum has low mechanical strength and corrodes rapidly in an acidic environment (e.g., pitted table surface). The use of aluminum is declining due to concerns for corrosion from cleaning and sanitizing solutions.

Brass (copper-zinc alloy) and **copper** have been used historically for construction of food contact surfaces. However, their use has diminished because of molecular reactions with food ingredients and corrosion resistance. Likewise, brass and copper can produce off-colors. They accelerate oxidation of ascorbic acid (vitamin C) and facilitate the onset of rancidity of seafood high in unsaturated fatty acids.

Other metals, like cast iron and black iron were first used for constructing of food contact surfaces during the Iron Age. Known as ferrous metals, this group corrodes following contact with water, hence, they may not be used in construction of food contact surfaces. Corrosion creates cavities that reduce the effectiveness of cleaning and sanitizing programs. However, cast iron may be used as a surface for cooking (U.S. Food Code 4-101.12).

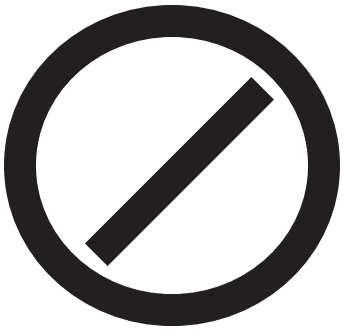
Historically, **wood** was the premier natural material of choice for constructing food contact surfaces (e.g., wooden baskets for seafood) as well as for floor construction. Advancements in development of other materials replaced wood. In most seafood processing plants, wooden floors are being replaced with concrete. However, wood continues to be used in design and construction of fermentation vats (or tanks) for low pH (inert to acidic environmental conditions) and high salt foods (corrosion resistant properties). In some instances, wooden boards or cutting boards are still used for trimming seafoods, but this generally is not recommended because normal usage leads to a rough surface containing places for food and microbial entrapment as well as making it difficult to clean and sanitize. The

suitability of wood depends on its quality and application. If a fine-grained hardwood is selected and properly maintained, it may be acceptable for some food contact uses. However, as a matter of policy, many health agencies do not consider wood to be impervious and strongly discourage its use in knife handles or other implements used directly for processing seafood.

2-12. Food contact surface materials which normally should be avoided if feasible:

- Wood (microbial concerns);
- Ferrous metals (corrosion concerns);
- Brass (variable corrosion resistance and product quality concerns); and
- Galvanized metal (corrosion and chemical leaching concerns).

Note: Certain state regulations may prohibit use of these materials as food contact surfaces in processing operations.



Plastic surfaces come in a variety of types approved for food processing. They offer a wide range of properties associated with temperature tolerance, machinability, hardness and flexibility. The decision to replace metal with plastics as a food contact surface is based on its mechanical strength and compatibility with processing requirements. The numerous merits of plastic often outweigh its few detriments.

Concrete is a common food contact surface made from a mixture of sand, limestone and stone. Concrete has been used for construction of water holding tanks, benchwork surfaces and flooring. The suitability of the surface depends on how it is finished. A smooth concrete surface is cleanable and repairable. Concrete surfaces can withstand corrosive action but may be weakened by caustic solutions. Select concrete formulations that are designed for the intended use. Because concrete is porous, certain concrete sealants are available for use in food plants. Tiles are also used in some processing plants, with grout forming the matrix between the tiles. As with concrete, grouts should be selected and applied to be as smooth as possible and, if necessary, sealed to prevent penetration of liquids and soil.

Outer garments, particularly aprons and gloves are considered food contact surfaces. In fact, any garment that routinely comes into contact with food must be considered. Frequent washing of gloves, aprons and other garments that may contact food, either directly or indirectly, is very important to ensuring a safe and high quality food product.

When not in use, gloves and garments should be stored in clean, dry areas separate from soiled clothing. Company policies should be established for buying, cleaning and storing clothing and gloves. These articles must be stored so that air circulates around them to facilitate drying. If folded or stacked in a pile while damp, large numbers of bacteria may grow on surfaces during storage.

Gloves, aprons and other garments should be properly designed for their intended use and be constructed of durable materials. For example, gloves made of non-absorbent materials (plastic or rubber) should be used. Cloth gloves should not be used with ready-to-eat products. Small, pre-existing holes in the glove material can result in bacteria being transferred from unwashed hands to the outside surface of the gloves contaminating the food product.

2-13. Storage of Clothing and Gloves:

- Store clothing and gloves in clean and dry locations;
- Ensure that clothing and gloves are not exposed to splash, dust or other contaminants; and
- Store clean garments separately from soiled garments and gloves.

Food processing companies should have a written policy (SSOP) for the replacement and reuse of clothing and gloves. Many companies issue gloves, aprons and boots to their employees to maintain control. They may require that issued items remain at the plant, and periodically inspect them for condition and replacement.

Equipment Design, Fabrication, and Location

2-14. Design and Install Food Contact Equipment to:

- Drain and not entrap soils;
- Provide access for cleaning and inspection; and
- Withstand plant environment.

Food contact surfaces should be constructed and designed so they can be readily cleaned and sanitized. Any seams or joints should be smoothly bonded. Equipment should be designed to avoid sharp angles or structures that hinder proper cleaning and sanitation. Surfaces should drain and not entrap soils. Although state and local regulations may have specific requirements, fixed equipment should be located far enough away from the processing walls and above floors to permit access for cleaning. Ensure that the supporting members are welded and do not provide places for insects to hide. Determine that food machinery is installed or relocated above floor level to facilitate maintenance, cleaning and sanitizing. If a solid floor-mounted base is required, the floor-machinery junction should be coved and tightly sealed. A recommended action would be to fill hollow floor bases with concrete. Stand supports utilizing a single pedestal with a round coved base sealed to the floor are preferred to the H-support often observed in food plants. Equipment should be designed with the fewest possible supports needed to meet safety and weight supporting requirements.

When purchasing machinery, observe positioning of electrical motors and control panels. Motors should be mounted on the equipment rather than on the processing floor, and never over production lines. Further, the electrical connections to motors should be waterproof and electrical conduits should be sealed to eliminate entrances for insects. The electrical wires should be grouped and protected within conduits to facilitate cleaning. Switch boxes should be positioned away from the processing equipment to allow for cleaning without electrical hazards. Floor-mounted units should have sloped upper surfaces for drainage, and conduit risers should enter the cabinet through the floor or from suspended grouped overhead wireways.

Conveyor belts should be made of non-absorbent and corrosive-resistant materials (e.g., nylon or stainless steel) that are easy to clean. Temperature considerations are important when selecting conveyor belts, as many plastic materials cannot withstand cryogenic temperatures used in freeze tunnels or the high heat of fryers. Motors and oiled bearings should be placed where oil and grease will not adulterate food product.

Water and steam should be supplied to food process machinery in pipes and tubes that are insulated if their surface temperature is hazardously high or sufficiently low to condense water vapor from the atmosphere resulting in a sanitation problem. Filters should be inspected monthly or more frequently if production necessitates.

During renovation, piping should be installed or relocated at least three inches from the walls and floors to facilitate thorough cleaning and sanitizing. Pipe hanger suspension rods should be round and suspended from braces.

Cleaning and Sanitizing Food Contact Surfaces

Clean, sanitary food contact surfaces are fundamental to the control of pathogenic microorganisms. The contamination of seafood through either direct or indirect contact with insanitary surfaces potentially compromises the safety of that product for consumption. The sanitary condition of food contact surfaces must be demonstrated for compliance with the sanitation control procedures. Effective sanitation standard operating procedures will outline the basic cleaning and sanitizing schedule (example, 2-28). Cleaning and sanitizing typically involves five steps: dry clean, pre-rinse (brief), detergent application (may include scrubbing), post-rinse and sanitizer application.

2-15. Five Steps of Cleaning and Sanitizing

1. Dry-clean;
2. Pre-rinse;
3. Detergent application, then;
4. Post-rinse; and
5. Sanitizing.

Cleaning

The importance of **cleaning** cannot be overemphasized. The effectiveness of a company's sanitation program more often relates to the implementation of proper cleaning procedures than to the type of sanitizer used. Simply rinsing equipment and processing surfaces with a chlorine solution, at any concentration, will not sanitize surfaces unless they are first cleaned with an appropriate detergent. The selection of detergents and sanitizers, their concentrations, and method of application will depend on several factors including:

1) nature of the soil;
2) degree of cleaning and sanitation required;
3) type of surface to be cleaned; and
4) type of equipment used for cleaning and sanitizing.

Sanitizers alone cannot be depended upon to remove microorganisms. Soil includes fish tissue, scales, process wastes, grease, bacterial films, dirt, etc. It is not always apparent. Certain bacteria, including some pathogens, may adapt to harsh conditions by forming a **biofilm**. They physically change, sending out tendrils that attach to the surface and to each other. They soon release a slime layer (a polysaccharide) which further protects them. Bacteria in a biofilm are not effectively removed with common soap and water cleaning procedures, and are up to 1,000 times more resistant to common sanitizers than when in a free state. A systematic cleaning routine should be followed to remove these biofilms and other soils.

Dry cleaning is simply using a broom, brush or squeegee to sweep up food particles and soil from surfaces. Too often processors use a water spray as a broom to push particulates. This practice significantly increases water consumption, contributes to water pollution or high water treatment costs, and creates problems associated with clogged drains and handling of wet solid wastes. It also tends to disperse dirt and bacteria to other areas of the plant (i.e., walls, equipment, and tables).

Pre-rinsing uses water to remove small particles missed in the dry cleaning step and prepares (wets) surfaces for detergent application. However, scrupulous removal of particulates is not necessary prior to application of detergent.

Detergents assist with particle removal and reduce cleaning time and water consumption. Each **detergent** is different and product directions must be followed. Many household cleaners and those intended for extensive hand contact are referred to as general purpose, or **GP** cleaners. They are quite mild and safe for use on painted or corrodible surfaces. They are rarely adequate for whole-plant use in commercial processing environments. However, they can be effective for lightly soiled surfaces or when given sufficient contact time and agitation (scrubbing).

Alkaline or chlorinated detergents are recommended for most processing plant applications and are more effective than general purpose cleaners against food soils. **Alkaline** detergents range from moderately to highly alkaline (caustic). **Chlorinated** products are usually more aggressive in loosening stubborn protein-based soils or for surfaces that are difficult to clean due to their shape or size, such as perforated storage crates (totes) and waste containers. They are also alkaline and many are very corrosive. They should not be used on corrodible materials, such as aluminum. Although chlorinated to assist with the chemical disruption of soils, they are detergents, not sanitizers.

A common strategy for operations currently using GP cleaners is to switch to an aggressive chlorinated detergent for a week or two, then maintain cleanliness with a somewhat milder alkaline detergent. Although most seafood processing soils contain mostly protein which is best removed with alkaline and chlorinated detergents, occasional cleaning with an **acid detergent** will remove inorganic mineral deposits (scale) and stains such as those associated with hard water.

In situations where exposure to excess alkaline or acid conditions are a problem, such as with wastewater discharge restrictions or equipment susceptible to corrosion, **enzyme detergents** may be an acceptable alternative. Because enzymes are specific to a given soil type, these detergents may not be as effective as other detergents for general plant use. Enzyme detergents are tailored for protein, oil or carbohydrate-based soils. Carbohydrate soils mostly occur where breadings, batters or starches are used. Moderately alkaline detergents are also generally effective for removing these materials. Smokehouse and cooker surfaces may be especially difficult to clean, requiring specialized highly-caustic cleaning chemicals and application methods.

2-16. Types of Detergents:

- General Purpose (GP);
- Alkaline;
- Chlorinated (chlorinated alkaline);
- Acid; and
- Enzyme.

For any given detergent and soil, cleaning effectiveness will depend upon several basic factors: contact time, temperature, physical disruption of the soil (scrubbing), and water chemistry.

2-17. A detergent's effectiveness varies with:

- Contact time;
- Temperature;
- Physical disruption (scrubbing); and
- Water chemistry.

Contact Time

Detergents do not work instantly but require time to penetrate the soil and release it from the surface. A simple strategy for increasing contact time is to set up **soak tanks or sinks**. Utensils, pans and other small pieces of equipment can be placed in tanks or sinks throughout the day. This often significantly reduces the need for scrubbing by hand later with a pad or brush. When larger pieces of equipment are dismantled for end of day cleaning, these too can be placed in designated soak tanks while

permanent, fixed pieces are cleaned in place. To avoid pitting or other damage, select an appropriate detergent when using extended soak times.

Obviously, large pieces of equipment or permanent fixtures cannot be submerged in a detergent solution. An effective method for increasing contact time on these surfaces is to apply the detergent as a **foam,** or less commonly, a gel. Air is incorporated with a high foaming detergent during application to produce a foam possessing the consistency of thin shaving cream. This clings to surfaces to be cleaned, even vertical surfaces which otherwise tend to dry prior to scrubbing or rinsing. Like other soils, dried detergent must be fully removed with fresh detergent prior to rinsing.

Foam applications serve other purposes as well. Detergent, water and air are mixed by the application equipment, producing consistent detergent concentration. It is also highly visible when applied, facilitating uniform coverage, optimal chemical usage and management oversight. Many types of foam **applicators** are available. They generally fall into three groups: 1) in-line systems; 2) precharged portable units; and 3) hose-end applicators. **In-line** foamers are connected to the plant water supply and draw detergent from a bulk container. Compressed air is injected into the line to create foam. The **portable foamers** consist of a tank, which is partially filled with measured detergent and water, then pressurized with compressed air. They are wheeled where needed and the contents delivered through a hose and nozzle similar to those used with the in-line models.

Hose-end foam applicators are similar in appearance to applicators sold at garden centers for home use with pesticides and fertilizers. Detergent is poured into a bottle, attached to a hose and delivered by opening a water valve. Air needed for foaming is drawn into the solution by venturi action. This method usually produces a wetter foam possessing poorer cling properties than the first two methods. It is the least expensive option but can be a significant improvement over applying detergent from pails or basins. Coverage is more uniform and some contact time extension is expected. When working with alkaline or chlorinated detergents, employees should wear appropriate clothing such as goggles, tall boots and aprons or full protective suits.

All cleaning methods, including foams and soaks require sufficient contact time to fully loosen and suspend soil. A moderately alkaline detergent will typically require 10-15 minutes to fully loosen most seafood processing soils. An extended time period (more than approximately 20 minutes) may allow detergents to dry and redeposit their soil load, or shorten equipment life. Therefore, contact time must be considered when selecting a detergent for any given application.

Washing methods are sometimes classified according to the design of the processing equipment to be cleaned. Some processing lines contain flumes or piping which can be cleaned without disassembling each section. This is known as clean-in-place or **CIP**. Closed processing systems are cleaned and sanitized by pumping one or more detergent solutions through the lines and associated equipment (such as any heat exchangers or valves) for prescribed intervals. The dairy industry uses this approach for cleaning fluid milk lines. Specially designed, low foaming detergents are usually required for CIP applications. When equipment must be disassembled for cleaning, it is referred to as clean-out-of-place, or **COP**.

2-18. Detergent application methods:

- ◆ Soak tanks;
- ◆ Foam;
- ◆ Automated systems;
  - CIP (clean-in-place); and
  - parts washers.
- ◆ Manual (pails).

Temperature

Most chemical activities increase with increasing temperature. This generally holds true with detergent efficiency, but with some important exceptions. Many styles of **steam cleaners** are available for heating detergent solutions and rinse water. Although, these can facilitate penetration and suspension of some food soils, hotter is not always better. Most raw seafood residues contain proteins which are readily denatured or cooked by hot water. This can occur even at solution temperatures near the cool end of commercial hot water cleaning (approximately 140°F). These cooked-on soils are especially stubborn and may require substantially more time and scrubbing effort to remove, or the use of a more aggressive detergent than otherwise would be necessary.

One strategy is to use water for initial wetting and detergent cleaning, then rinse at 140-160°F. This improves effectiveness with less risk of cooking seafood residues onto plant surfaces. For certain applications, such as cookers and smokehouses, highly caustic detergent or alkali (caustic soda) is heated to 180°F or hotter. These conditions chemically alter and disperse soils such that denatured food residues are not likely to develop.

Disruption (scrubbing)

The selection of proper detergents and application methods will minimize the need for manual scrubbing, however physical disruption of soils is frequently required to assist with soil removal. To be effective, cleaning aids must be carefully selected. Appropriate methods include brushes, pads and pressure spray depending on the application. In many cases, manual cleaning is only needed occasionally.

2-19. Example Cleaning Procedure:

A processor applies an alkaline foam detergent to equipment every day. The detergent is allowed to stand and then is rinsed without scrubbing. Actual scrubbing with brushes or pads takes place only once each week.

2-20. Physically removing soils:

- Brushes – proper stiffness;
- Pads – proper cutting properties; and
- Pressure spray – moderate pressure.

Brushes and pads can be highly effective but only if properly selected. If additional pressure is needed to remove difficult soils, bristles may splay, resulting in significantly reduced efficiency. In these cases, a stiffer brush is needed. However, excessively stiff bristles may not conform to surfaces or may require excessive pressure and effort. A stiff brush on a long handle can quickly fatigue the user. Brushes and brooms should be color coded and only be used in specified areas. Brushes, brooms, or pads used in raw areas should **never** be used in processing areas for ready-to-eat products.

Pads have become very popular as manual cleaning aids. They readily conform to surfaces and usually require only light pressure to be effective. They may improve the feel of the user as compared to a brush. For example, fingers on a pad can be run under the lip of a processing table with improved contact. Pads are also appropriate for cleaning knives and other small implements. Pads are synthetic materials designed for a specific cleaning application. Two pads similar in appearance may differ greatly in performance. They should have sufficient cutting properties to loosen soils without scratching plant surfaces. They are often specified according to the material or hardness of surfaces to be cleaned. **Steel wool should not be used** because it's too abrasive and can cause rusting. When hand detailing equipment, employees should wear protective gloves to prevent contact with harsh chemicals.

Pads, brushes and brooms should be dedicated to tasks for which they are designed. Not only is cleaning effectiveness optimized, but cross contamination between areas of the plant can be minimized. A system of **color coding** can be very helpful for training and management oversight. Color coded pads are available to facilitate proper selection. For example, red cleaning aids could be selected for use in the raw materials area, white aids in the finished product area, and black aids with drains. The colors in each area designate some predetermined use, such as scrubbing relatively hard or soft surfaces.

2-21. Pads, brushes and brooms should be dedicated to tasks for which they are designed:

- Optimizes cleaning effectiveness; and
- Minimizes cross-contamination between areas of the plant.

Cleaning aids which retain water, such as **sponges**, wiping cloths and mops should not be used for routine cleaning in processing plants. After just one use, they may harbor large numbers of bacteria, including species known to cause disease. They are very difficult to clean and sanitize, and frequently

contaminate the very surfaces you wish to sanitize. Although they are convenient for picking up excess water or sanitizer solution, a better option is to use a sanitized squeegee to strip surfaces of liquids, or select equipment that drains by design.

2-22.

Cleaning aids which retain water, such as sponges, wiping cloths and mops should not be used for routine cleaning in processing plants.

After use, cleaning aids should be thoroughly cleaned, rinsed, sanitized and stored so that they dry. Hang brooms off of the floor to store. Brushes and squeegees can be hung on a wall or board to dry. Alternatively, they can be stored in a fresh sanitizer solution. Store pads in fresh sanitizer unless they can be stored so that air circulates freely around them and they dry between uses.

Removing detergent with high pressure spray is another method for physically disrupting loosened soils. **Pressure washers** are widely available and are popular, especially for difficult to reach surfaces such as metal mesh belts. Like steam cleaners however, they are inappropriate for general use. Pressure spray kicks up water and associated soil, creating an aerosol or mist, which can carry onto previously cleaned surfaces. Generally, plants are cleaned from the top down, starting just above the splash zone on walls and finishing with the floors. If a high pressure spray hits the floor, recontamination of cleaned food contact surfaces is highly likely. One disease-causing bacteria, *Listeria monocytogenes*, thrives in damp environments such as floor drains. This microorganism is not permitted in ready-to-eat seafoods at any level. Therefore, never direct pressurized spray into floor drains. This practice creates a mist that spreads the pathogens over a large area.

Spray systems can be characterized as:
1) high pressure, high volume;
2) high pressure, low volume;
3) low pressure, high volume; and
4) low pressure, low volume.

The first of these, high pressure (may exceed 1,000 psi) combined with high water flow, can damage equipment (for example, may cut through grease seals) and be dangerous to employees. Excessive water usage is usually to be avoided since it contributes to high operating costs, and does not significantly assist with soil removal. This mostly limits food processing spray systems to low volume delivery at water pressures generally not exceeding approximately 200 psi.

Some processors may find they require nearly continuous cleaning throughout the day. Processing line belts or product totes that are cycled frequently for reuse may be most efficiently cleaned with **automated equipment**. These range from fixed spray heads, scrapers and rotary brushes used to minimize soil build-up during operation to fully automated cleaning cabinets and container washers. Fully automated equipment is often designed for a particular function, such as washers that position, wash, rinse, sanitize and drain product totes (lugs). Small parts washers are available for automated cleaning of utensils and disassembled equipment parts.

Cleaning and Water Chemistry

Water is seldom pure. It commonly contains various impurities, which may alter the effectiveness of cleaning (and sanitizing) chemicals. **Hard water** contains calcium and magnesium salts, which react with cleaners and diminish their effectiveness. The reacted constituents drop out of solution forming a mineral-complex residue that may trap food soils and become increasingly difficult to remove. Most modern industrial detergents contain conditioners to minimize these problems but, in some locations, water chemistry may be a factor in the proper selection of cleaning agents. At a minimum, greater detergent concentrations are likely to be needed when used with hard water. Certain other **minerals**, such as iron or manganese may stain plant fixtures and equipment. Water chemistry is especially important when selecting sanitizers. Major suppliers of cleaning and sanitizing chemicals are usually the best source for specifying products appropriate for given water conditions. Various treatment systems are commercially available for control of water hardness and other water impurities. Often, such pretreatment of plant water will significantly improve the performance of cleaning and sanitizing chemicals.

Post-rinsing

During post-rinsing, water is used to remove detergent and loosen soil from food contact surfaces. This process prepares the cleaned surfaces for sanitizing. All the detergent must be removed in order for the sanitizing agent to be effective.

Sanitizing

After food contact surfaces are cleaned, they must be sanitized to eliminate or at least suppress potentially harmful bacteria. Many types of chemical sanitizers are commercially available. They may or may not require rinsing before the start of processing, depending upon the sanitizer and its concentration (see table 2-26). All sanitizers must be approved for use in food establishments and be prepared and applied as labeled. The U.S. Environmental Protection Agency and the U.S. Food and Drug Administration regulate sanitizers used in food processing facilities (21 CFR 178.1010). The regulatory reference can be confusing. Questionable chemicals should be checked against local authorities.

2-23. Sanitizing follows proper cleaning:

1. Dry-clean;
2. Pre-rinse;
3. Detergent application;
4. Post-rinse;
5. Sanitizing.

5th Step!

Application Methods

Sanitizing is a relatively simple process involving the application of an approved sanitizer to equipment and other plant surfaces that have already been cleaned. Recommended methods for applying sanitizers include **proportioners and applicators**, low pressure **tank sprayers,** and **dips**. The proportioners and applicators can be installed in-line or at separate stations. A range of procedures can be used, from manual mixing to fully automated systems that draw from bulk containers. Some sanitizers, such as quaternary ammonium compounds (quats or QACs), may be applied as a **foam** with the same

equipment used for detergent foam application. This increases contact time (important for these sanitizers) and visually confirms coverage. Complete coverage is required with any sanitizer, but excessive spraying only wastes chemical.

2-24. Sanitizer Mixing and Application:

- In-line proportioners/applicators;
- Station proportioners/applicators;
  - Hand and footbath sanitizers;
- Foamers;
- Tank sprayers (low pressure); and
- Dips.

Sufficient contact time and coverage is sometimes best assured by the use of sanitizer dip tanks for utensils and equipment parts. As with corrosive detergents, care is needed with many sanitizers to avoid damaging equipment. For control of common soil microorganisms, such as *Listeria* and *E. coli*, footbaths are frequently part of a plant sanitation program. Most often, they are simply trays containing sanitizer solution positioned at room entrances, which coat the soles of footwear and the wheels of carts. Some systems continually replenish the solution or direct the overflow from hand sanitation dips into a footbath. Footbaths must be level to be effective.

Sinks and cleaning stations can be supplied with **proportioning devices** that mix and deliver sanitizer in the proper concentration. Many designs draw from a bulk container or reservoir, which minimizes maintenance, controls chemical usage and may reduce monitoring. Systems are commercially available which allow the user to select detergent, sanitizer or fresh water when filling a basin or spraying processing room surfaces. Proportioning devices need to be monitored to be sure that they are working properly and delivering the expected concentration of sanitizer. Sanitizers must be used at concentrations that are effective without violating regulatory limits (2-25). Certain sanitizers are commonly applied at higher concentrations when used on floors, cooler walls and other non-food contact surfaces.

Types of sanitizers

Unfortunately no ideal sanitizer exists for every requirement. Some common sanitizers and their advantages and disadvantages are listed in overhead 2-26. **Chlorine** and products that produce chlorine comprise the largest and most common group of food plant sanitizing agents. Chlorine sanitizers are effective against many types of bacteria and molds. They work well at cool temperatures and tolerate hard water. They are also relatively inexpensive. Household bleach is a solution of sodium hypochlorite; a common form of chlorine, although use of common bleach is prohibited in certain states. Look for labeled instructions since not all sources are approved for use in food processing.

Chlorine exists in more than one chemical state when dissolved in water. The effectiveness of chlorine sanitizers is proportional to the percentage of hypochlorous acid in solution; the most effec-

tive chemical form of chlorine. The percentage of hypochlorous acid increases as alkalinity (pH) is decreased. The pH of some water supplies is artificially elevated, which reduces the effectiveness of chlorine. However, chlorine is very unstable at low pH and may dissipate prematurely without killing bacteria. Also, at a pH below 4.0, chlorine gas (i.e., World War I mustard gas) is formed which is highly toxic and corrosive. For these reasons, chlorine sanitizers are usually applied at alkaline pH or in a formulated form to maintain a near neutral pH. Also, never mix chlorine and ammonia. The mixture could be hazardous.

Chlorine sanitizers have certain disadvantages however. They can be corrosive to equipment, and may form organochlorine by-products of environmental concern in effluent. Chlorine is inherently unstable in solution, requiring frequent monitoring and replenishing to maintain adequate concentration. A common misconception is that the chlorine content of a sanitizer can be confirmed by its odor. Chlorine is chemically tied up in the presence of most soils, hence the need to thoroughly clean and rinse prior to applying sanitizer. A used solution that still smells like chlorine may have little or no active chlorine available for killing microbes.

Of the total chlorine applied, the amount of free chlorine available for killing microorganisms is the amount in excess of that combined (bound) with soils and other compounds. This background level of inactivated, bound chlorine is known as chlorine demand. As chlorine is added to a system, the point at which the chlorine demand is satisfied and free and measurable levels of chlorine persist, is known as the breakpoint. Breakpoint chlorination is the process of using just enough chlorine to achieve a persistent level of measurable chlorine in solution. At times, it may be necessary to add more chlorine to meet chlorine demand. Test strips must be used to determine if proper chlorine levels have been achieved.

2-25. Sanitizer Concentrations Commonly Used in Food Plants

Sanitizer	Food Contact Surfaces	Non-food Contact Surfaces	Plant Water
Chlorine	100-200* ppm	400 ppm	3-10 ppm
Iodine	12.5-25* ppm	12.525 ppm	
Quats	200* ppm	400-800 ppm	
Chlorine dioxide	100-200* ppm	100-200 ppm	1-3 ppm
Peroxyacetic acid	200-315* ppm	200-315	

*The higher end of the listed range indicates the maximum concentration permitted without a required rinse (surfaces must drain)
Includes mix of oxychloro compounds
Source: 21 CFR 178.1010

The **hypochlorites** are the most common chlorine sanitizers. They are available as liquid concentrates or in dry/granular form. The granular or powdered chlorine products are sometimes referred to as **bleaching powders**. Do not confuse these with scouring powders, which generally should not be used in food processing facilities. Chlorine also can be injected as a **gas** directly into designated water lines. This is a low cost option for large operations but is potentially hazardous and requires specially designed equipment. Stabilized **organic** forms of chlorine are also available. Mixing vinegar or another acid with chlorine sanitizers is occasionally proposed for increasing their efficacy but the practice is *not* recommended. Not only may the chlorine dissipate prior to making contact with microorganisms but dangerous chlorine gas may form if the solution is excessively acidified.

Chlorine dioxide functions differently from other chlorine-based sanitizers. It does not form hypochlorous acid but dissolves in water to produce a solution possessing strong oxidizing properties. It can be more effective than chlorine in terms of ability to kill or reduce bacteria, and it retains some antimicrobial function in the presence of organic soils. For that reason, it is particularly useful for destroying bacteria in bio-films. It is also less corrosive to stainless steel and less pH sensitive than chlorine. Unfortunately, chlorine dioxide is very unstable and must be generated on-site. It is potentially explosive and very toxic if improperly controlled—important considerations when selecting this sanitizer. A relatively safe method for obtaining chlorine dioxide is by mild acidification of an aqueous solution of sodium chlorite commonly known as stablized chlorine dioxide (21 CFR 173.325).

2-26. Types of Sanitizers

Sanitizer	Forms/Description	Advantages	Disadvantages
Chlorine	Hypochlorites Chlorine gas Organic chlorine, e.g., Chloramines	-Kills most types of microorganisms -Less affected by hard water than some -Does not form films -Effective at low temperatures -Relatively inexpensive -Concentration determined by test strips	-May corrode metals and weaken rubber -Irritating to skin, eyes and throat -Unstable, dissipates quickly -Liquid chlorine loses strength in storage -pH sensitive
Iodophors	Iodine dissolved in surfactant and acid	-Kills most types of microorganisms -Less affected by organic matter than some -Less pH sensitive than chlorine -Concentration determined by test strips -Solution color indicates active sanitizer	-May stain plastics and porous materials -Inactivated above 120 NF -Reduced effectiveness at alkaline pH -More expensive than hypochlorites -May be unsuitable for CIP due to foaming
Quaternary Ammonium Compounds	Benzalkonium chloride and related compounds, sometimes called quats or QACs	-Non corrosive -Less affected by organic matter than some -Residual antimicrobial activity if not rinsed -Can be applied as foam for visual control -Effective against Listeria monocytogenes -Effective for odor control -Concentration determined by test strips	-Inactivated by most detergents -May be ineffective against certain organisms -May be inactivated by hard water -Effectiveness varies with formulation -Not as effective at low temp. as some -May be unsuitable for CIP due to foaming
Acid-Anionic	Combination of certain surfactants and acids	-Sanitize and acid rinse in one step -Very stable -Less affected by organic matter than some -Can be applied at high temperature -Not affected by hard water	-Effectiveness varies with microorganism -More expensive than some pH sensitive (use below pH 3.0) -Corrodes some metals -May be unsuitable for CIP due to foaming

2-26. Continued

Sanitizer	Forms/Description	Advantages	Disadvantages
Peroxy Compounds	Acetic acid and hydrogen peroxide combined to form peroxyacetic acid	-Best against bacteria in biofilms -Kills most types of microorganisms -Relatively stable in use -Effective at low temperatures -Meets most discharge requirements -Low foaming; suitable for CIP	-More expensive than some -Inactivated by some metals/organics -May corrode some metals -Not as effective as some against yeasts and molds.
Carboxylic Acid	Fatty acids combined with other acids; sometimes called fatty acid sanitizers	-Kills most types of bacteria -Sanitize and acid rinse in one step -Low foaming, suitable for CIP -Stable in presence of organic matter -Less affected by hard water than some	-Inactivated by some detergents -pH sensitive (use below pH 3.5) -Less effective than chlorine at low temp. -May damage non-stainless steel materials -Less effective against yeasts and molds than some
Chlorine Dioxide	A gas formed on-site and dissolved in solution or by acidification of chlorite and chlorate salts	-Kills most type of microorganisms -Stronger oxidizer (sanitizer) than chlorine -Less affected by organic matter than some -Less corrosive than chlorine -Less pH sensitive than some	-Unstable and cannot be stored -Potentially explosive and toxic -Relatively high initial equipment cost
Ozone	A gas formed on-site and dissolved in solution	-Kills most type of microorganisms -Stronger oxidizer (sanitizer) than chlorine and chlorine dioxide	-Unstable and cannot be stored -May corrode metals and weaken rubber -Potentially toxic -Inactivated by organic matter (similar to chlorine) -pH sensitive -More expensive than most
Hot Water / Heated Solutions	Water at 170 - 190^{N}F	-Kills most types of microorganisms -Penetrates irregular surfaces -Suitable for CIP -Relatively inexpensive	-May form films or scale on equipment -Burn hazard -Contact time sensitive; inappropriate for general sanitation

Quaternary Ammonium Compounds, sometimes known as quats or QACs have made a comeback in recent years after generally falling out of favor with many microbiologists. They require a relatively long exposure time to achieve significant kill. This is not always a problem however since they are very stable and will continue to kill bacteria long after most sanitizers lose their effectiveness. Because of this residual effect, even in the presence of some soil, they are often selected for footbaths, floors and cooler surfaces. They are quite effective against the pathogen *Listeria monocytogenes* and are commonly used in facilities that produce ready-to-eat products, such as crabmeat, smoked fish and cooked shrimp. Unfortunately, quats also can be selective in the types of microorganisms they kill. Some food processors who have switched to quats have experienced problems with the establishment of coliform or spoilage organisms in the environment, which may then transfer to products. A strategy which is often successful involves alternating with another sanitizer one or two times per week. Detergents must be thoroughly rinsed from surfaces prior to applying quats or the sanitizer will be chemically neutralized.

Iodine-based sanitizers, known as iodophors, are formulated with other compounds to enhance their effectiveness. They offer many desirable features in a sanitizer. They kill most types of microorganisms, including yeasts and molds, even at low concentrations. They tolerate moderate contamination

with organic soils, are less corrosive and pH sensitive than chlorine and are more stable during storage and use. They are also less irritating to skin than chlorine and are often selected for hand dips. Iodophors have an amber to light brown color when properly diluted which can be useful for monitoring since color indicates the presence of active iodine. Test strips are also available for more precise monitoring. The principal disadvantage of iodophors is staining, especially of plastics. The problem is minimized by carefully controlling concentrations. Iodophors take longer to kill microorganisms at low temperatures than does chlorine and is rapidly vaporized and inactivated above 120°F. Iodophors must be specially formulated for use with hard water.

Acid sanitizers include **acid-anionic** and **carboxylic and peroxyacetic acid** types. Their principle advantage is in applications requiring stability at high temperatures or in the presence of organic matter. Being acids, they remove inorganic soils, such as hard water mineral scale, while sanitizing. They are most commonly used in CIP or mechanical cleaning systems. The carboxylic acid sanitizers, commonly known as fatty acid sanitizers, are generally more effective than acid-anionics against a range of microorganism types. The most recent class of acid sanitizers are the peroxy compounds, or **peroxyacetic acid**. Produced by combining hydrogen peroxide and acetic acid, peroxyacetic acid is highly effective against most microorganisms of concern to seafood processors, especially in biofilms, which would otherwise protect bacteria. They are fast acting even at low temperatures, tolerate some organic soil and degrade to form environmentally safe byproducts. However, water chemistry is important since these sanitizers are inactivated by certain metal ions, such as iron, and become quite corrosive when mixed with water containing high chloride levels, for example wells with salt intrusion problems.

Other sanitizing agents include ozone, ultraviolet light and hot water. **Ozone** is an unstable oxidizing gas that must be generated on-site, contributing to its relatively high cost. It is a more aggressive sanitizer than chlorine but requires careful monitoring to prevent the release of excessive levels of the toxic gas. Ozone, like chlorine, is dissipated when in contact with organic soils. It can be injected into water systems, as an alternative to chlorine gas, to make it safe for processing.

Ultraviolet (UV) irradiation is sometimes used for treating water, air or surfaces that can be positioned in close proximity to UV generating lamps. Ultraviolet does not penetrate cloudy liquids or below the surface of films or solids. It has no residual activity and cannot be pumped or applied onto equipment like most chemical sanitizers.

Confirming Sanitation

Monitoring to assure a clean and sanitary processing environment is required by the Seafood HACCP Regulation. Each facility must show evidence, such as completed forms, indicating that appropriate cleaning and sanitation procedures are followed. Consistent results are achieved through development of effective methods, thorough training of employees, management oversight and testing. Evaluation methods usually include some combination of daily and periodic activities. Examples of the former include visual confirmation that company SSOP are followed, and the use of test strips or colorimetric kits for measuring sanitizer concentration (Form 2-8).

Test strips are the most popular method for determining sanitizer concentrations. Most are very rapid, low cost, require no laboratory equipment or chemicals, can be performed on-site, and require very little training to use. Typically, the strips are simply dipped or soaked directly in the solution to be tested. A change in strip color indicates the presence of sanitizer; the shade or intensity of which relating

to concentration. This is determined using a color comparator or chart as a reference. Unfortunately, test strips may not be available for all of the sanitizers used in your facility. Also, they generally provide only an estimate of sanitizer concentration or a concentration range. For more precise measurement, a variety of test kits are available. These often involve adding one or more reagents (laboratory chemicals) to a sample of the solution to be tested. Concentration may relate to the color produced or to the quantity of reagent required to produce a visible change in the sample.

Periodically, the effectiveness of cleaning and sanitizing plant surfaces can be evaluated by using **contact plates** containing bacterial growth media. These test procedures are very simple and require no special equipment and little training. Most contact plates are simply touched to the surface to be tested (e.g. table tops and door handles) then covered with a protective cap, film or sleeve. After the plates are stored for a couple of days, any detected bacteria will appear as small circles. The number of circles appearing on the plates provide a good indicator of the effectiveness of cleaning and sanitizing efforts. An alternative method involves swabbing an area with a sterile applicator, which is transferred into a liquid medium for plating later or swabbed directly onto a solid growth medium. These methods make excellent training tools for employees and assist in the evaluation of cleaning methods and materials. Because high numbers of bacteria are grown on these plates, safe handling and disposal is essential. Store and view them in an area away from processing areas and soak them in strong sanitizer before disposal. Wash and sanitize hands thoroughly after handling plates.

Microbiological testing is relatively slow and does not reveal problems in time to correct them prior to processing. Recent alternatives, such as luminometry, are gaining acceptance in the food processing industry. **Luminometry** (bioluminescence) is based on the enzymatic reaction responsible for a firefly's light. In this testing process, the brightness of light is proportional to the amount of bacteria and food debris on the surface. In a typical test, a food contact surface is swabbed following sanitation. Material picked up on the swab is placed inside an instrument that measures light production. The instrument generates a value related to the quantity of cellular material, such as bacteria. In some instances the residual food can provide a high reading when the microbial load on the surface is quite low. Microbiological techniques, are required for more specific testing such as coliform bacteria count.

2-27. Periodic Confirmations for Sanitization:

- ◆ Microbiological Enumeration;
  - • Contact plates;
  - • Swabs; and
- ◆ Luminometry.

2-28. Typical Cleaning and Sanitizing Schedule

For table tops (processing tables, packing tables, etc.) and other surfaces that come directly into contact with the product, XYZ Shrimp Company uses 25 ppm iodine, 100 ppm chlorine or 200 ppm quat sanitizer. At these levels, surfaces do not require rinsing the next day. For non-food contact surfaces, such as floors and walls, sanitizer concentration is doubled. Note that quats have detergent-like properties and may be slick when floors are wet. Some newer generation products, such as peroxyacetic acid sanitizers, have been shown to be highly effective against a broad spectrum of bacteria while complying with environmental discharge standards. Peroxyacetic acid may be substituted as directed on the product label declaration for any of the standard sanitizers previously listed. Manufacturers recommendations are followed closely for all sanitizers. When sanitizers are used in footbaths, dips or as an applied sanitizing solution the concentration is confirmed at least every four hours using test strips.

The following program is implemented for each operation:

A. Truck Beds (for raw shrimp):

Daily:
Inside of truck bodies are rinsed, then sprayed daily with 400 ppm quat after all shrimp are unloaded.

Weekly:
Clean using detergent, then sanitize (equivalent to 200 ppm chlorine).

B. Raw Shrimp Receiving (Daily):

1. Workers are restricted from entering processing area directly from truck off-loading area (footbath, hand-washing and appropriate clothing required).

2. Area is cleaned and sanitized at the end of operations using the five part process. The floors are sanitized using low pressure spray of 400 ppm quat or equivalent Peroxyacetic acid.

3. Plastic crates (shrimp totes) are placed in soak tank containing chlorinated detergent or hand scrubbed with detergent, then rinsed and sanitized with 200 ppm quat or equivalent peroxyacetic acid.

C. Processing Room:

Daily**:**

1. Product pans, totes, knives, deveining tools and similar implements are placed in a detergent soak tank. At the end of clean-up they are rinsed and dipped in sanitizer (100 ppm chlorine or equivalent peroxyacetic acid or iodophor).

2. Processing waste is removed from area, and tables and floors are dry cleaned.

3. Tables, graders, conveyors, wash tank, etc. are thoroughly cleaned and sanitized using the five part system (note item 4 for exception). Since these are food contact surfaces, a sanitizer concentration of 100 ppm chlorine, 25 ppm iodine, 200 ppm quat or equivalent peroxyacetic acid is used. If process intervals exceed six hours, graders and tables are cleared of product and the surfaces sanitized. Excess sanitizer applied during breaks is removed with paper towels or a sanitized squeegee.

4. The tiled processing table is dry cleaned, rinsed then cleaned with a general purpose (GP) detergent and scrubbed with brushes and/or pads. It is rinsed, then sanitized with low pressure spray application of 100 ppm chlorine, 25 ppm iodine, 200 ppm quat or equivalent peroxyacetic acid. If process intervals exceed six hours, it is cleared of product and the surfaces sanitized. Excess sanitizer applied during breaks is removed with paper towels or a sanitized squeegee.

5. Floors, splash zone of walls (four feet above floor), and sinks are cleaned daily using the five part system and sanitized with 400 ppm quat or other double strength sanitizer (e.g. peroxyacetic acid).

6. Footbaths are located at the outside entrances to the processing area. The bath is maintained at 400 ppm quat. The concentration of quat in the bath is checked at the start of the work day before the workers arrive and every two hours during times of use.

7. Hand dips are located at handwashing stations and in the processing area: approximately one for every 15 employees They are maintained at 25 ppm iodine using a commercial iodophor. The concentration of iodine in the dips is checked at the start of the work day before the workers arrive and every two hours during times of use.

Weekly:

1. Acid detergent is substituted for alkaline or chlorinated detergents on the wash tank, graders, conveyors and stainless steel tables to remove water scale and brighten surfaces.

D. Product Cooler (refrigerated staging area):

Twice Weekly:

1. Dry cleaned after area is emptied of product.

2. Floors sprayed with 400 ppm quat.

3. Pallets are cleaned and sanitized.

Weekly:

Thoroughly cleaned and sanitized using the five part system.
Monthly:
The drip pan from the evaporator is sanitized by pouring quat (400 ppm) into the pan. The ceiling is wiped with 400 ppm quat.

Annually:
The evaporator is thoroughly cleaned using hand brushes etc. It is sanitized with 400 ppm quat. **Be sure electricity is turned off and disconnected.**

F. Pallets, Dollies, Miscellaneous:

Daily:

1. Cleaned with detergent and sanitized with 400 ppm quat or equivalent.

2. Door and water faucet handles are detergent cleaned daily, hand detailed with mild, abrasive pads and sanitized.

3. Doors and walls are cleaned and sanitized daily in splash zone (four feet to floor) and weekly in higher areas.

2-29.

Sanitation Control Guide

Entry date:	Cleaning and Sanitizing	FDA Key Condition No. 2

Concern: Food contact surfaces may appear clean but harbor pathogens

Examples:

Bacteria may be present in crevices, overlapping joints or hidden areas difficult to inspect. Clearly visible surfaces may be coated with invisible biofilms containing bacteria. Some surfaces may be stained with minerals or water scale making visual inspection difficult. Chemicals used for cleaning and sanitizing must be appropriate and effective without harming the equipment, utensils or environment of discharge.

Controls and Monitoring:

Visual check of all food contact surfaces for proper cleaning and sanitation. Use a strong flashlight or other shadow-free lighting source when inspecting hidden areas. Disassemble and inspect food contact equipment to identify areas which may trap soils. **Frequency: Daily pre-op for raw seafood line, plus after every break for ready-to-eat lines.**

Confirm visual checks with bacterial contact plates or luminometer. **Frequency: Monthly or more frequently if results indicate.** (note: swabs are used in place of contact plates in areas that are difficult to access). Luminometer — weekly or more frequently if results indicate.

Visually confirm that proper procedures, equipment and chemicals are used for cleaning and sanitizing. Use five-step approach. Use test papers to record proper strength for sanitizers. **Frequency: Daily pre-op for raw seafood line, plus after every break for ready-to-eat line.**

- Pans, knives, and other utensils are placed in a soak tank containing general purpose detergent (concentration controlled by proportioner). After soaking 30 minutes the items are rinsed and dipped in sanitizer (100 ppm chlorine).
- All processing waste removed from work areas, and tables and floors are dry cleaned. Tables are cleaned with general purpose detergents, followed by rinsing, then exposure to 200 ppm chlorine. Floors, splash zone of walls (4 feet above floor), and sinks are cleaned then sanitized with 400 ppm quats or 200 ppm chlorine.
- Periodically (weekly) use an acid detergent to remove stains and scale
- Periodically switch (monthly) to another class of sanitizer to prevent selecting tolerant types of

Recommended Corrections:

If surfaces are inadequately cleaned, fully reclean and resanitize following the five-step procedures. Check sanitizer concentrations. Train employees semi-annually or more frequently if indicated by monitoring.

Records:

Daily Sanitation Control Record
Contact Plate Record (confirmation)
Employee Training Record

2-30.

Sanitation Control Guide

Entry date:	Processing equipment and utensils	FDA Key Condition No. 2

Concern:

Pits, cavities, cracks, scales or breakage on processing equipment or utensils used as food surfaces.

Examples:

Food contact surface is collecting debris, shows signs of rusting or is difficult to clean due to rough or worn surfaces. Pits, cuts and cavities on food processing surface (e.g., food cutting boards). Water scale on surface of processing tables after cleaning and sanitizing due to standing water and high mineral content.

Controls and Monitoring:

Examine all food contact surfaces (i.e., tables, flumes, knifes, cutting boards, etc.) for condition and ability to clean and sanitize. Observe inclination of processing tables surface to allow proper drainage. **Frequency: Daily pre-op and monthly through entire plant.**

Recommended Corrections:

Replace or repair food processing surfaces (e.g., cutting boards). While replacing ensure that they are made of hard, nonporous, water impervious synthetic materials that can be cleaned and sanitized.

Records:

Daily and Monthly Sanitation Control Records

Chapter 3

Prevention of Cross-Contamination

Introduction

This area relates to employee practices to prevent product contamination; physical separation of raw and cooked product; and plant design to prevent contamination. This chapter focuses on microbial or bacterial cross-contamination. Chemical cross-contamination is discussed in Chapter 6.

3-1. Key Sanitation Condition No. 3:

- Employee 'practices' to prevent cross-contamination;
- Separation of raw and ready-to-eat foods; and
- Plant design to prevent cross-contamination.

Raw seafood, like other raw foods, contains microorganisms that cause food spoilage and may also contain harmful microorganisms called pathogens that are bacteria or viruses that can cause human illness. These microorganisms can come directly from the marine environment or from contamination that occurs after fish or shellfish products have been harvested. Likewise, people who work in food handling operations can harbor pathogens on their skin and hands, and in their digestive system or respiratory tract. These bacteria and other microorganisms have no means of their own to move around in a food handling or processing plant. They must be physically carried from one place to another.

Hands, gloves, outer garments, utensils, food contact surfaces of equipment that come in contact with waste, the floor, or other unsanitary objects can contribute to product contamination. Employees should be trained on how and when to properly wash and sanitize their hands, gloves, and outer wear, as well as equipment such as shovels and buckets that come into contact with the floor or waste. It is also very important to stress that in order to effectively clean equipment, all residual product must be removed; the equipment must be cleaned with hot water and/or the appropriate detergent; and the equipment must then be sanitized.

3-2. Cross-Contamination:

Cross-contamination is the transfer of biological or chemical contaminants to food products from raw foods, food handlers, or the food handling environment. The type of cross-contamination most frequently implicated in foodborne illness occurs when pathogenic bacteria or viruses are transferred to ready-to-eat foods.

Monitoring

3-3. Goal:

To prevent cross-contamination from insanitary objects to food, food-packing materials and other food-contact surfaces, including utensils, gloves and outer garments, and raw product to cooked product or ready-to-eat products.

To effectively control cross-contamination you need to evaluate and monitor all areas of the processing or food handling environment to ensure that raw products are not handled, stored or processed in a manner that will allow them to contaminate cooked, ready-to-eat, or heat-and-serve products that will not be fully cooked before they are eaten. A designated individual should check at the beginning (pre-op) of the work day or shift to ensure that all planned processing or handling activities involving raw products will be conducted in areas that are adequately separated from processing activities that involve cooked or ready-to-eat products. The same individual should also periodically check to ensure that these activities remain segregated throughout the work period. If employees move between these areas or activities they should wash and sanitize their hands before handling cooked or ready-to-eat products. Footbaths or other control measures should also be used when employees move from one area to another. Movable equipment, utensils or conveyances should be cleaned and sanitized before they are moved from raw product areas to areas where cooked or ready-to-eat products are handled or processed. Product storage areas such as coolers should be checked daily, generally about half way through the work period and at the end of the work day, to ensure that cooked and ready-to-eat products are adequately separated from raw products.

3-4. Common Daily Sanitation Practices to Prevent Cross-Contamination:

- Adequate separation of raw and cooked or ready-to-eat product handling or processing activities;
- Adequate separation or protection of products in storage;
- Food handling or processing areas and equipment adequately cleaned and sanitized;
- Employee hygiene, dress and hand washing practices;
- Employee food handling practices and utensils; and
- Employee traffic or movement about the plant.

A supervisor or other designated employee should monitor employee hygiene at the beginning of the workday or shift and periodically during the work period. This evaluation should ensure that employees are clean, are wearing appropriate attire including hair restraints if necessary, and are not wearing jewelry or other ornamentation that could contaminate products. Employee practices should also be monitored periodically throughout the work period to ensure that cross-contamination does not occur. Employee practices that should be monitored include: that gloves are used appropriately; that hand wash and sanitizing procedures are used properly; that inappropriate activities such as drinking, eating, and smoking do not occur in food handling areas; and that employees working with raw products do not go to or move equipment to areas where cooked or ready-to-eat products are handled.

NOTE: In accordance with the federal Seafood HACCP regulations, the monitoring of employee hand washing "practices" is associated with the key sanitation condition number 3 for prevention of cross-contamination (Chapter 3). The monitoring for the "condition" of the hand washing facilities are monitored under the key sanitation condition number 4 for maintenance of hand washing, hand sanitation and toilet facilities (Chapter 4).

In most cases, hand washing practices in bathrooms cannot be easily monitored. However, hand washing practices at hand washing stations in or near food handling or processing areas can be visually monitored. The individual conducting sanitation monitoring should check to be sure that employees are washing their hands and are using appropriate hand washing and sanitizing techniques. The frequency of this monitoring activity will vary depending on the situation. Hand washing and sanitizing practices can be most readily observed and monitored before work begins, when employees return to food handling or processing after lunch or other breaks in the shift or work day, after using the bathroom or handling insanitary objects like garbage. Locations where employees may move from raw product handling areas to cooked or ready-to-eat product handling areas should receive particular attention. Daily monitoring of hand washing may need to be conducted more frequently in operations that are handling or processing cooked or ready-to-eat foods. When employees are observed not washing and sanitizing their hands when required or using inadequate hand washing and sanitizing practices, supervisors should require an immediate correction.

3-5. Examples of Poor Employee Practices:

- Handling raw product, then handling cooked product;
- Working near or on the floor, then handling product;
- Handling trash cans, then handling product;
- Returning from restrooms without washing hands;
- Shovel used to handle floor waste, also used to handle product;
- Scratching face, then handling product; and
- Touching unclean cooler door handle, then handling product.

Corrections

Corrections to any unsatisfactory activity or condition which could result in cross-contamination should be made in a timely manner to prevent potential contamination of food and food contact surfaces. When conditions in food handling areas are observed that could lead to cross-contamination, processing or handling activities should stop until the area is cleaned and sanitized and raw and finished product handling or processing activities are adequately separated. If the potential for cross-contamination is observed in storage, cooked or ready-to-eat products should be immediately separated or covered. If contamination is likely, the product should be segregated and held until a decision is made regarding the safety of the product. Based on this decision, the product may be diverted to a safe use, reprocessed, or discarded if contamination has occurred.

3-6. Corrections Concerning Cross-contamination:

- Stop activities, if necessary, until the situation is corrected;
- Take steps to prevent contamination from re-occurring;
- Evaluate product safety and, if necessary, divert, reprocess or discard affected products; and
- Document what corrections were taken.

If improper employee hygiene or poor food handling practices are observed, employees should be corrected. In particular, when employees are observed not washing and sanitizing their hands when required or using inadequate hand washing and sanitizing practices, supervision should require an immediate correction. Expected performance and practices should be reviewed. Employees should also

understand why these practices could cause the products that they are handling to be unsafe and the potential impacts on the company and their job. Taking advantage of these teachable moments can often be more effective than formal training programs which should also be utilized when employees are hired and periodically to ensure employees understand what is expected of them.

Records

The daily sanitation control records should include space for observations and corrections for each of the potential opportunities for cross-contamination that could occur in the plant. The record should allow the individual conducting the monitoring activities to note if conditions are satisfactory or unsatisfactory, when monitoring was conducted and who conducted it. The record should provide space to describe any corrections that are taken when unsatisfactory conditions are observed. Although the recording form may list designated periods for checks (e.g., morning and afternoon shift), concerns for cross-contamination should extend through the entire work day. Records are only required for regularly scheduled monitoring.

In the example daily sanitation control record (3-8), this company has modeled a form to check for pre- and post-operational concerns for cross-contamination in storage, and during routine practices throughout the work day. In contrast, some firms may choose to record storage checks at the end of work (post-op) and at the beginning of the next work day (pre-op). This may seem redundant, but for some companies events or changes can occur in storage between work days. Likewise, a company should conduct monthly monitoring of the entire processing operation (3-9) to check and correct any potential cross-contamination problems due to the basic plant layout (e.g., food flow vs. personnel traffic).

3-7. Continuous monitoring for cross-contamination:

Although the recording form may list designated periods for checks (e.g., morning and afternoon shift), concerns for cross-contamination **should extend through the entire work day.**

3-8.

DAILY SANITATION CONTROL RECORD

Report Date: 10/22/99

Firm Name: Any Seafood Co., Inc.

Line 1: Raw Seafood (not ready-to-eat)
Line 2: Ready-to-eat

Firm Address: Anywhere, USA

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time: 6:00P	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hoses (S/U)	U					Replaced backflow prevention on hose faucet
2) Condition and Cleanliness of Food Contact Surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U)	S					
Line 2: (S/U)	S		S	S		
◆ Sanitizer Strength Sanitizer Type: Chlorine Strength: 100-200 ppm						
Line 1: (ppm)	100					
Line 2: (ppm)	100		100	50		Adjusted to 100 ppm before use (4:40 P)
◆ Gloves and aprons clean and in good repair Line 1: (S/U)		U				Replace 10 pairs of gloves (8:30 A)
Line 2: (S/U)		S				
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U)		S	S	U		Two staff told to change aprons before changing work stations
◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U)			S	S		Raw fillets stored above & dripping onto boxed smoked fish. Product checked and repacked.
◆ Unpackaged cooked products separated from raw products (S/U)			S	S	U	

S = Satisfactory / U = Unsatisfactory

3-9.

Monthly Sanitation Control Record

Report Date: 1/21/99

Firm Name: Any Seafood Co., Inc

Firm Address: Anywhere, USA

Sanitation Area	Decision	Comments/ Corrections
1) Safety of Water ◆ Safe and sanitary source (S/U) (annual) ◆ No cross-connections in hard plumbing (S/U)	S U	Municipal water bill and analysis on file (1/10/99) Requested installation of air gap in water line used to fill new thaw tank
2) Condition and Cleanliness of Food Contact Surfaces ◆ Processing equipment and utensils in suitable condition (S/U)	U	Replaced cracked cutting board at station no. 2.
3) Prevention of Cross-contamination ◆ Physical conditions of plant and layout equipment (S/U)	S	Put new storage table in receiving area to segregate raw product.

S = Satisfactory / U = Unsatisfactory

Additional Comments:

Air gap installed 1/22/99

Need plan to phase out all wooden cutting boards

Added another table to keep incoming raw and cooked fish separate at receiving (11:30).

Signature (Initials) BSJ

Background

Understanding Cross-Contamination

The type of cross-contamination most frequently implicated in foodborne illnesses occurs when pathogenic bacteria or viruses are transferred to ready-to-eat foods that are not usually cooked before they are eaten. This is a particular concern for seafood products that have been previously thermally processed to produce a final, edible product (e.g., cooked shrimp, prepared entrees, smoked fish, dried seafoods, seafood salads and surimi analog product). It is also a significant concern for seafoods that are eaten with any prior exposure to heat (e.g., raw molluscan shellfish, raw fish and pickled fish). The possible consequences for foodborne illnesses are obvious if these products contain potential pathogen microbial contaminates.

3-10. Typical raw or ready-to-eat seafood that will not be cooked before they are eaten:

- Cooked shrimp and other cooked shellfish;
- Smoked fish or shellfish;
- Dried, pickled or cured fish or shellfish;
- Surimi products;
- Seafood salads;
- Heat and serve entrees;
- Molluscan shellfish to be eaten raw; and
- Finfish to be eaten raw (sashimi or sushi).

3-11. Sources of pathogens that could cross-contaminate finished products:

- Seafood handlers and other plant personnel;
- Raw seafood;
- Equipment or utensils; and
- Processing plant environment.

Both employees and food contact surfaces often serve as vectors for the transmission of pathogenic microorganisms to 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. Raw products in the plant may also serve as a reservoir of pathogenic microorganisms so care must be taken to prevent cooked or ready-to-eat products from being contaminated by raw products,

food contact surfaces used for raw products or employees who handle raw products. Both employees and equipment that touch raw seafood can transmit these microorganisms to the cooked product. 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 or other ready-to-eat products should be physically separated from each other. Raw and ready-to-eat products should also be physically separated in storage coolers. The movement of employees and equipment should be controlled or procedures such as using boot dips or requiring hand washing when employees move from one area of the plant to another should be used.

Product Flow and Plant Layout

3-12. **Goal:**

To ensure that product handling and/or processing procedures prevent the cross-contamination of seafood products by raw materials, ingredients or processing operations.

3-13. **Separate raw and ready-to-eat products:**

- When receiving products or ingredients;
- During processing or handling operations;
- During storage; and
- During shipping.

Special procedures or designated areas for handling raw materials, ingredients, or packaging materials may be necessary to prevent the contamination of finished products. Unit processing operations may also need to be physically separated. Processing should be conducted in a way that will prevent the finished product from being contaminated by raw materials, processing machinery, conveyors, utensils, other equipment, garbage or other refuse such as fish entrails, racks or other inedible portions of the raw materials used in the plant. It is critical that procedures are in place to ensure that raw and cooked or ready-to-eat products are adequately separated during receiving and storage as well as during processing. Raw and ready-to-eat products should be physically separated in coolers or other storage areas. It is generally a good idea to have separate coolers for storage of raw products and finished ready-to-eat products. If this is not possible or feasible, ready-to-eat products should be stored in a designated area in the cooler that is separated by a barrier or enough distance so that raw products cannot drip or splash onto ready-to-eat products. Ready-to-eat products should never be stored below raw products that could drip onto them. Ingredients and packaging materials should also be stored in appropriate areas of the plant to prevent raw products, garbage or other materials from contaminating them.

3-14. **Prevent cross-contamination during processing by:**

- ◆Designating separate areas for handling raw and ready-to-eat products;
- ◆Controlling the movement of equipment from one area to another; and
- ◆Controlling the movement of employees from one area to another.

Careful design of product flow and unit processing operations is also necessary to prevent cross-contamination. Ideally raw products and finished ready-to-eat products should be handled in separate areas of the plant. Processing operations should be designed in such a way that products, equipment and personnel do not move from raw to finished product handling areas. Special attention should be given to controlling the movement of equipment and personnel from areas where raw product is handled to areas where ready-to-eat products are handled. Some operations have utilized color coding schemes to ensure that equipment used in raw product handling areas which could contain pathogens is not used in areas where ready-to-eat products are handled. Attention should also be paid to the movement of employees from one area of the plant to another. Food handlers working with raw products can carry bacteria from these products on their hands, clothes, and shoes that could contaminate ready-to-eat product handling areas. Techniques such as requiring employees to wash their hands, changing outer garments, or walk through sanitizing foot baths when moving from raw product handling areas to ready-to-eat product handling areas can be used to minimize the potential for cross-contamination.

Employee Hygiene and Food Handling Practices

3-15. **Goal:**

Prevent cross-contamination of seafood products by ensuring that employees follow proper personal hygiene and hand washing practices.

By far the easiest area of cross-contamination to identify is personnel practices. In contrast, it is also the hardest to control. For example, personnel often have the ability to contaminate product, simply by touching it with their hands. Gloves are frequently used to avoid direct hand contact, but gloves may create a sense of false security for food handlers. Dirty gloves, like dirty hands, can also contaminate products if they are not kept clean. In many instances, the use of gloves may not be practical, and effective hand washing and sanitation procedures must be used. Even when gloves are used, hands should be thoroughly washed and sanitized prior to covering the hands.

3-16. Employee hygiene practices:

- ◆ Hand washing;
- ◆ Jewelry;
- ◆ Hair/beards;
- ◆ Footwear;
- ◆ Eating, drinking, smoking, etc.; and
- ◆ Other - perspiration, cosmetics, medicine.

Current GMP require that all persons working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

1. Washing hands thoroughly (and sanitize if necessary to eliminate undesirable microorganisms) in a designated hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

2. Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

3. Wearing, where appropriate and in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints. Hair in food can be a source of both microbiological and physical contamination. Food handlers should be required to keep their hair clean and appropriate hair and/or beard restraints should be worn at all times in food handling areas.

4. Boots may transfer contaminants to workers hands when dressing or may track contaminants into processing areas. An ideal situation would be for plant employees to change their footwear before starting work. In some plants, employees use the same footwear inside and outside the plant environment. Under such a situation processors producing cooked product must take precautionary measures and enforce the use of footbaths containing sanitizers. When the plant has visitors, visitors must also adhere to the same control procedures. Often this can be accomplished by using disposable cotton boots or rubber footwear. Under such situations the visitor does not have to walk through a footbath.

5. Eating food, chewing gum, drinking beverages, or using tobacco should not occur in any areas where food may be exposed or where equipment or utensils are washed. Healthy people frequently

harbor pathogens in their mouth and respiratory tract. When activities such as eating, drinking, or smoking that involve hand to mouth contact occur, pathogens can be transferred to employees' hands and then to the food products that they handle. These activities should not occur in food handling areas, and hands should be washed when employees return to work areas after engaging in these activities.

6. Implementing any other precautions necessary to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

Establishing an Effective Hand Washing Program

Training for hand washing is an essential part of your sanitation program. Seafood processing plants must manage a large work force that directly handle finished product and food contact surfaces. Unfortunately, it takes only a few untrained or uncooperative employees handling finished seafood product to create a sanitation contamination problem.

3-17. Reason for a Hand Washing Program:

- Many employees do not routinely wash their hands;
- Hand washing is not conducted properly; and
- Many employees do not understand the importance of hand washing.

The importance of hand washing is not fully appreciated by most employees. Data show that a significant number of food handlers do not wash hands or do not use proper techniques. After all, bacteria and other contaminants are not visible. Unfortunately, when an untrained employee can not see contaminants on their hands, they may assume there is no need to wash them. For the most part, supervisors can not determine the condition of employees' hands by visual inspection. Systematic procedures and a routine hand-washing schedule are essential to controlling the spread of contaminants from employees' hands to food.

Many employees do not comprehend the serious role their hands play in cross-contamination, that is, touching an unsanitary object or substance and then touching food product. In order to have an effective hand-washing program, employees must grasp the importance of keeping themselves clean. For example, an employee may think that because hands are routinely washed and sanitized that food product can be safely handled. However, if this same employee is habitually touching soiled or contaminated clothing, hair or face and other body parts, then cross contamination is occurring.

Hand washing procedures must be part of an on-going training program. This is especially true for new employees. Supervisors should discuss requirements of the company before the employee is assigned to a workstation and keep a record of the points discussed. Overhead 3-21 provides a sample form that could be used for initial training of employees during the interview process.

How to Wash Hands

The primary purpose of hand washing is to remove unwanted microbiological and other contaminants. The ability and dexterity of employees' hands to manipulate objects that remove edible seafood products from shells, exoskeletons and bones is remarkable. However, as they become soiled, the very features that make hands useful tools may also interfere with cleaning and sanitizing them. For example, all hands have wrinkles, crevices, rills and fingernails. The arms attached to hands may sweat and may have hair. It is important to wash and sanitize all of these areas to remove accumulated material.

3-18. How to wash hands:

- Remove jewelry;
- Wet hands with warm water (110°
- Lather and rub using warm water;
- Rinse;
- Dry with disposable paper towels; and
- Avoid recontamination.

To facilitate the proper washing and sanitizing of hands, remove jewelry and other objects that hide and protect soil and bacteria. Generally, wedding bands (without gemstones) are acceptable and can remain on the finger. Watches, bracelets and other arm and wrist ornaments are not acceptable. Fingernails should be clipped and filed. Hands should not have any infections, wounds or sores since hand washing will not remove pathogenic bacteria associated with these conditions. It is important to stress to employees that merely dipping hands in a sanitizing solution will not properly rid hands of pathogenic microorganism. Soils, such as fats, oils and other dense, difficult to remove materials, will protect microorganisms from sanitizing agents.

The U.S. Public Health Service's Food Code is a useful publication for food processors (see Sources for Additional Information). It provides sound recommendations for sanitary production of food and food products including recommendations on washing hands. The most current issue of the Food Code specifies that "…employees shall clean their hands and exposed portions of their arms with a cleaning compound in a lavatory…by vigorously rubbing together the surfaces of their lathered hands and arms for a least 20 seconds and thoroughly rinsing with clean water. Employees shall pay particular attention to the areas underneath the fingernails and between the fingers."

Generally, the first step for manual hand washing is to thoroughly wet exposed arms and hands (including the back of the hands) with warm water. Warm water is essential in good hand washing procedures. It softens some soil material and facilitates emulsification of soil material with the cleaning compound. The Food Code requires that water be capable of achieving a temperature of at least 43°C (110°F) for this purpose.

Introduce ample soap and vigorously rub hands together to produce an abundant lather. Liquid soap in a dispenser is probably the least messy way to distribute soap onto hands. There are many

types of soaps and detergents available for hand washing. Processors must be sure that soaps and detergents intended for hand washing facilities are specifically for hands. Some detergents intended for equipment cleaning might not be suitable for hands. A good basic soap is adequate for most operations.

Many food processing firms use antimicrobial soaps and detergents. Studies have shown that antimicrobial soaps are no more effective than regular soaps in removing unwanted microorganisms from hands and exposed arms. Care should be exercised if an anti-microbial soap is routinely used as part of a company's hand washing program. It is possible that improperly used or overused that some of these soaps may cause skin irritations.

Supervisors should demonstrate and have employees practice the lathering procedures and the feel of the proper temperature of water. In addition, employees should be able to determine proper timing through practice. Remember, lathering and rubbing for 20 seconds followed by a thorough rinsing in clean water is a minimum. Employees may have to scrub longer depending on the soil build up or contamination of hands. Done properly, hand washing will remove most microorganisms of concern.

Clean, disposable paper towels should be available to thoroughly dry hands after washing. Improperly drying of hands could actually create cross-contamination problems. For example, properly cleaned hands dried on soiled or contaminated towels would negate the best-intended hand washing effort.

How to Sanitize Hands

When necessary, hand sanitizing should immediately follow hand washing. Hands should be dipped in a sanitizing solution to destroy any remaining microorganisms. Hand sanitizing solutions should be safe to the individual and should not pose a contamination problem for the food product. There are numerous types of commercially available hand sanitizing solutions. Most use chlorine or iodine as the active ingredient. The Food Code provides some guidelines in using hand-sanitizing solutions. Sanitizing agents are regulated and must be used according to regulations and manufacturers recommendations. Typically, hand sanitizers are composed of chlorine compounds or iodine compounds intended for that purpose. According to the Food Code, a chemical hand sanitizing solution used as hand dip shall be maintained clean and at a strength equivalent to at least 100 ppm chlorine. These hand dips may be in individual bowls at workstations or in faucets near workstations. Since some sanitizing agents dissipate over time, they must be monitored often to ensure proper strength. Keep in mind that concentrated sanitizing solutions are considered to be toxic substances and must be properly stored.

When to Wash and Sanitize Hands

An essential part of an effective hand-washing program is knowing when to wash and sanitize. It is not enough to instruct employees to wash when hands are dirty or soiled. There are specific times to wash. The Food Code gives the following times for employees to wash their arms and hands:

3-19. When to wash arms and hands:

- After touching bare human body parts other than clean hands and clean exposed portions of arms;
- After using the toilet room;
- After coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
- After handling soiled equipment or utensils; and
- During food preparation, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks.

Management's Role in Employee Hygiene

Management must also play a role in helping employees prevent cross-contamination. Management should provide a clear understanding of the personal hygiene practices and company policies regarding illness and other health conditions such as infected wounds that could contaminate products. (Refer to Chapter 7 for complete information on managing employee health conditions.) Policies that provide reassurance that employees will not lose their job if they report that they have an illness or a communicable disease should be developed. A protocol for employees posted in work areas that describe good personal hygiene and health practices is recommended. Training programs designed to help employees understand exactly what is expected of them and why it is important should be utilized. Management should continually emphasize how important it is for employees to maintain a high level of cleanliness and good health and should serve as role models for good work habits and acceptable hygienic practices. Management should also take steps to ensure that visitors are required to follow the same hygienic practices as employees, and have policies in place that prevent unauthorized personnel from being in food handling areas. Supervisors should utilize one-on-one training when employee practices are corrected to ensure that they understand what practices or behavior is required and why those practices are important to the company and the safety of the products they are producing. Management should also assume responsibility for providing properly located and maintained facilities and equipment that will allow employees to adhere to personal hygiene requirements including:

a) Dressing or changing rooms that are adequate and properly maintained.
b) Laundry services and/or uniform services as necessary.
c) Designated employee areas for breaks where eating and drinking is allowed.

3-20. Management's role:

- Set policies that outline personal hygiene expectation;
- Set policies for employees with an illness (Chapter 7);
- Training;
- Monitoring and enforcement; and
- Provide adequate employee facilities.

Sources of Additional Information

Current Good Manufacturing Practices, Part 110, Title 21, Code of Federal Regulations.

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3-21. Employee orientation form for hand washing and sanitizing requirement.

EMPLOYEE TRAINING
HAND WASHING AND SANITIZING

Preparation of Hands:

- No jewelry (other than a plain wedding band) is permitted. This includes watches and bracelets;
- Fingernails will be clipped and filed for each cleaning; and
- Hands and arms must be free of infections and sores.

How to Wash Hands:

- Use ample liquid soap from a dispenser;
- Use warm water;
- Lather exposed arms and hands for 20 seconds by vigorously rubbing;
- Thoroughly rinse hands in clean, warm water (110° F);
- Use foot operated faucets to prevent re-contamination of hands;
- Dry hands thoroughly and properly dispose of paper towels;
- Dip hands in sanitizing solution; and
- Do not touch unsanitary objects.

When to Wash Hands:
Wash hands routinely:

- After touching bare human body parts;
- After using the toilet room;
- After coughing, sneezing, using a handkerchief or disposable tissue;
- After handling soiled equipment or utensils;
- Immediately before engaging in food preparation;
- During food preparation as often as necessary to remove soil and contamination; and
- Other activities that may require it.

I have discussed and understand the above teaching points on hand washing and the use of toilets in this facility.

Employee_____ Date_____

3-22.

Sanitation Control Guide

Entry date:	Hand Washing	FDA Key Condition No. 3

Concern: Proper Hand Washing Procedures

Examples:

Employees fail to wash and sanitize hands before work or as needed periodically during the work day.
Employees fail to wash and sanitize hands after working with raw product before working with ready-to-eat products.

Controls and Monitoring:

Observe employee hand washing and sanitizing practices at hand wash stations in food handling or processing areas. **Frequency: Daily, Start-up and after every break.**

Conduct periodic hand washing and sanitizing training for all employees and reinforce with posted reminders. **Frequency: When employed and semi-annual.**

Recommended Corrections:

Immediately require employees to re-wash and sanitize hands when improper hand washing practices are observed. Evaluate situation to determine if products may have been contaminated. Provide posted signs reminding employees of proper procedures. Conduct one-on-one training as appropriate, and schedule training programs as necessary.

Records:

Daily Sanitation Control Record
Employee Training Records

3-23.

Sanitation Control Guide

Entry date:	Cross-Contamination	FDA Key Condition No. 3

Concern: Prevent Cross-Contamination by Plant Personnel

Examples:

Personal hygiene requirements are not being followed. Employees working in food handling areas are observed wearing inappropriate jewelry, not using appropriate hair or beard restraints, or are wearing clothes or shoes that are not appropriate and/or clean. Employee practices that involve hand-to-mouth contact such as eating, drinking, and smoking are observed in the product handling areas of the plant. Employees are using unacceptable food handling practices that could contaminate products such as touching ready-to-eat foods with their bare hands or returning ready-to-eat products that have dropped onto the floor to production lines.

Controls and Monitoring:

Check employee personal hygiene practices including use of clean and acceptable clothing, aprons or other work garments. **Frequency: Daily, after every break.**

Check personal habits of employees to ensure that eating, drinking, smoking or other activities that involve hand-to-mouth contact are not conducted in food handling areas. **Frequency: Daily, between every break.**

Check employee food handling practices and ensure that there is no direct hand contact with cooked or ready-to-eat foods. **Frequency: Daily, between every break.**

Monitor employee movements from raw product to ready-to-eat product handling areas to ensure that proper hand washing and other measures such as the use of footbaths used to prevent cross-contamination are being properly used. **Frequency: Daily, after every break.**

Recommended Corrections:

1. Require employees to immediately correct deviations from expected personal hygiene practices. Ask employees to review company personal hygiene policies. Provide training. 2. Require employees to immediately stop smoking, drinking, or eating in food handling areas. Inform employees where and when these activities are permitted and provide training as necessary to reinforce how this behavior can contaminate foods. 3. Immediately correct employees who are observed using poor food handling practices. Provide instructions and on site training if necessary. If contamination is likely, segregate the product and evaluate its safety. 4. Require any employees who go from raw product handling areas to finished product handling areas to wash their hands before handling ready-to-eat products. Provide instructions or training as necessary as incidents occur.

Records:

Daily Sanitation Control Record
Employee Training Records and/or Pre-employment agreements

3-24.

Sanitation Control Guide

Entry date:	Cross-Contamination	FDA Key Condition No. 3

Concern: Prevent Cross-Contamination by Processing and Handling Procedures

Examples:

1. A conveyor belt used for packaging raw fish fillets is not cleaned and sanitized before employees start packaging smoked eels and surimi. 2. Raw clams and oysters are stored in the cooler under a shelf that contains boxes of raw fish on ice. 3. Customer orders that include ready-to-eat foods like smoked fish, cooked shrimp, and raw clams and oysters are assembled on the same table where raw fish are filleted. 4. Hand trucks used to unload boxes of raw fish from delivery trucks to storage coolers are then used to transfer trays of smoked eels and salted fish to finished product storage cooler. 5. Pallets of boxes to be used to pack consumer retail packages of cooked shrimp and surimi are stored on the floor in the fish filleting area of the plant.

Controls and Monitoring:

1. Stationary equipment such as conveyor belts are cleaned and sanitized after being used for raw products and before it is used for ready-to-eat products. **Frequency: Daily, every 4 hours.**
2. Product storage coolers should be routinely monitored to ensure that raw and ready-to-eat products are stored separately or when stored together are physically separated by enough space to prevent raw products from dripping or splashing onto ready-to-eat products. **Frequency: Daily, every 4 hours, and post-op.**
3. Food handling and processing activities should be routinely monitored to ensure that raw and ready-to-eat foods are handled and/or processed in designated areas that are adequately separated to prevent cross-contamination. **Frequency: Daily, every 4 hours, and semi-annual review for plant operations.**
4. The movement of equipment from raw product handling areas to ready-to-eat product handling areas should be controlled. Ideally equipment should not move from one area to another or should at least be cleaned and sanitized before using for ready-to-eat products. **Frequency: Daily, every 4 hours, and semi-annual review for plant operations.**
5. Product packaging materials used for ready-to-eat products should be stored in designated areas where it is not exposed to contamination from raw products or other contaminants found in or outside the plant.

Recommended Corrections:

1. Ensure that this equipment is properly cleaned and sanitized after being used for raw products and before it is used for ready-to-eat products. Discard products that are likely to have been contaminated and train employees as necessary. 2. Move ready-to-eat products to designated area of cooler physically separated by a barrier or enough space to ensure that raw products cannot drip or splash onto ready-to-eat products. Discard products that were likely to have been contaminated and provide employee instruction or training as needed. 3. Physically separate food handling or processing operations for raw products from ready-to-eat products. Discard products that are likely to have been contaminated, and provide employee instructions and/or training as necessary to ensure that this practice does not reoccur. 4. Properly clean and sanitize the work surfaces and instruct employees that such equipment must be cleaned and sanitized before moving from one area to another. Discard products that likely to have been contaminated.
5. Discard, recondition, or divert contaminated packaging material or ingredients to an acceptable use. Ensure that there are adequate storage areas for these materials.

Records:

Daily Sanitation Control Record
Employee Training Records

Chapter 4

Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities

Introduction

This area is intended to primarily deal with the location, 'condition' and maintenance of hand washing, hand sanitizing and toilet facilities. This topic is closely linked with the monitoring requirements under key sanitation condition number 3 (Chapter 3) for monitoring hand washing and sanitizing practices to prevent cross-contamination.

4-1. Key Sanitation Concern No. 4:

- Condition of hand washing facilities;
- Condition of hand sanitizing facilities; and
- Condition of toilet facilities.

Seafood processing facilities generally require a significant amount of manual handling of the products. Cutting, filleting, shucking, peeling, sorting, and packaging are just a few examples of the manual steps that are conducted with worker hands. In some instances, cooked ready-to-eat products such as crab meat and crawfish meat must be handled to remove and to package the meat. Other seafood value-added products (soups, smoked fish, sandwiches, and other specialty items) may also be handled by workers without any further cooking prior to consumption. Unfortunately, human hands are used for more than just handling seafoods by plant workers. They may be used to greet others (handshake), combing hair, scratching, eating during a lunch break, handling unsanitary objects, and going to the toilet. When engaged in these activities, hands may become contaminated with harmful microorganisms and substances.

Obviously, hand washing is necessary in a facility that produces raw fishery products. Hand washing and hand sanitizing are necessary for those employees who handle ready-to-eat food, or food packaging materials or food contact surfaces for ready-to-eat products. If hands are not properly washed and sanitized prior to handing seafood products, they may serve as a significant source of pathogenic

microorganisms or chemical contamination on finished seafood products. Food processing facilities must establish an effective hand washing program. The availability and maintenance of toilet facilities are essential parts of the hand washing program in order to prevent the spread of filth and pathogenic organisms throughout the plant.

Monitoring

4-2. Goal:

To support a necessary hand washing program to prevent the spread of filth and potential pathogenic organisms about the processing area or to foods.

Hand washing facilities in bathrooms and hand wash stations in food handling and processing areas should be checked at least once per day to ensure that they are clean, functioning properly, and have the necessary supplies including hot water, soap, disposable paper towels, and a trash receptacle. More than one daily check may be required for certain food operations. The type and frequency of the periodic checks would depend on the food products and processing methods. For example, the daily sanitation control record (Form 4-6) includes checks every 4 hours for proper sanitizer concentration at the hand sanitizer stations or dips used by the employees processing the ready-to-eat foods (Line 2). The concentration of hand sanitizer in hand dip stations should be checked with appropriate test strips when they are made up and as often as necessary depending on the sanitizer, and how often hand dips are used. One daily pre-op check for the hand washing and sanitizing stations is sufficient for employees working on raw, to-be-cooked seafoods (Line 1).

Similar checks for the condition and functionality of the toilet facilities should be made at least once per day. A pre-op check would be the best time to check to assure the toilet facilities are in proper running order for the employees before and during the work day. Toilet facilities must always be in proper working order and cleaned routinely to avoid serious contamination. As part of the daily SSOP checklist, each toilet must be flushed and examined for proper function. A back flow or blocked toilet can spread fecal contamination throughout the plant. Improper conditions could contribute to possible cross-contamination for both ready-to-eat and raw, to-be-cooked seafoods.

4-3. Recommended monitoring for hand washing, hand sanitizing and toilet facilities:

- Condition of hand washing facilities;
- Condition of hand sanitizing facilities; and
- Condition of toilet facilities.

NOTE: In accordance with the federal Seafood HACCP regulations, the monitoring of employee hand washing " practices" is associated with the key sanitation condition number 3 for prevention of cross-contamination (Chapter 3). The monitoring for the "condition" of the hand washing facilities are monitored under the key sanitation condition number 4 for maintenance of hand washing, hand sanitation and toilet facilities (Chapter 4).

Corrections

4-4. Corrections:

- Fix or replenish supplies in toilets and hand wash stations;
- Discard and make up new hand sanitizer solutions if concentration is incorrect;
- Record observations of corrections taken when unsatisfactory coditions are observed
- Repair improperly working toilets.

When monitoring of toilet and hand washing facilities indicate that supplies are lacking or they are not functioning properly, the problem should be corrected immediately by fixing broken equipment or replenishing supplies. When inadequate hand sanitizer concentrations are observed, a new hand dip with the proper concentrations should be provided and employees should be required to rewash and sanitize their hands if necessary. A responsible, knowledgeable individual should assess the situation to determine if any products have been contaminated. If so, the affected products should be segregated and reprocessed, diverted to a safe use, or discarded. Supervision should take advantage of this "teachable moment" to explain why and how to maintain proper sanitizer concentrations.

Records

4-5. Records for the condition of facilities to clean and sanitize hands, and for toilets:

- Condition and location of hand washing stations or sinks, and toilet facilities;
- Condition and availability of hand sanitizer stations, sinks or dips;
- Concentration of hand sanitizers; and
- Corrections taken when unsatisfactory conditions are observed.

A Daily Sanitation Control Record (Form 4-6) or log should include space for recording observations that indicate the facility conditions are checked periodically during the day. The records should identify where and when each observation was made, whether the conditions observed were satisfactory or unsatisfactory, the actual concentration of any sanitizers observed, any necessary corrections, and by whom and when was the observation made. The federal HACCP mandate emphasizes the need for "positive" records or actual measures such as the concentration of hand sanitizers.

4-6.

DAILY SANITATION CONTROL RECORD

Report Date: 10/22/99

Firm Name: Any Seafood Co., Inc.

Line 1: Raw Seafood (not ready-to-eat)
Line 2: Ready-to-eat

Firm Address: Anywhere, USA

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time: 6:00P	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hoses (S/U)	U					Replaced backflow prevention on hose faucet
2) Condition and Cleanliness of Food Contact Surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U)	S					
Line 2: (S/U)	S		S	S		
◆ Sanitizer Strength Sanitizer Type: Chlorine Strength: 100-200 ppm						
Line 1: (ppm)	100					Adjusted to 100 ppm before use (4:40 P)
Line 2: (ppm)	100		100	50		
◆ Gloves and aprons clean and in good repair Line 1: (S/U)		U				Replace 10 pairs of gloves (8:30 A)
Line 2: (S/U)		S				
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U)		S	S	U		Two staff told to change apron before changing work stations
◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U)			S	S		Raw fillets stored above & dripping onto boxed smoked fish. Product checked and repacked.
◆ Unpackaged cooked products separated from raw products (S/U)			S	S	U	

4-6. (Continued)

Daily Sanitation Control Record (page 2)

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time:	Comments and Corrections
4) Maintenance of Hand-washing, Hand-sanitizing, and Toilet Facilities						
◆ Hand-washing and hand-sanitizing stations adequate						
• Hand-washing station Line 1: (S/U)	S					
Line 2: (S/U)	S					
• Hand-sanitizing station						
Sanitizer Type: Iodine						
Strength: 12.5-25 ppm						
Line 2: (ppm)	25		25	25		Filled empty soap dispensers in men's bathroom
◆ Toilets clean, properly functioning, and adequately supplied (S/U)	U					
5) Protection from Adulterants and 6) Labeling, Storage, and Use of Toxic Compounds						
◆ Product protected from contamination (S/U)						
◆ Cleaning compounds, lubricants, and pesticides labeled and stored properly (S/U)						
7) Employee Health Conditions						
◆ Employees do not show signs of medical problems (S/U)						
8) Exclusion of Pests						
◆ Pests excluded from processing area (S/U)						

S = Satisfactory / U = Unsatisfactory

Signature or initials BSJ

Background

Careful planning is required in providing and equipping hand washing and toilet facilities. Plant managers should consider both location and number. The Food Code is an excellent reference for basic considerations. In addition, local and state regulations may require the establishment of hand washing and toilet facilities in specific locations based on the number of employees. In general, hand-washing facilities are located either in the toilet room or immediately outside the door. Some employers require that employees not only wash hands after going to the toilet in the wash room but also wash them again at a designated hand-wash sink in the processing room. This double wash procedure gives greater control of potential fecal cross-contamination and provides an opportunity for the employer to observe and monitor post-toilet hand washing. This is extremely important, since one of the most serious sources of contamination may come from employees that fail to properly wash their hands after using the toilet.

Hand washing facilities should be located in other areas of the processing facility to provide ample opportunities for employees to wash. Hand washing facilities should be dedicated solely for that purpose. They should never be used to wash dishes, utensils or other items that may soil or contaminate the area. Hand washing should never be conducted in sinks used for food preparation or in sinks used for cleaning and sanitizing the plant. In addition, if hand washing facilities are used for other purposes, it could prevent or delay employees from using them. Each hand washing facility should be provide the following items at all times:

4-7. Recommendations for Hand Washing Facility:

- Clean at all times;
- Strategically located as per regulations, near bathrooms and entrances to the processing area;
- Dedicated to hand washing only;
- Liquid soap in dispenser;
- Hot water (43°C or 110°F);
- Use of disposable paper towels or air blowers; and
- Adjacent hand sanitizing facilities.

Hand Sanitizers

There are numerous types of commercially available hand sanitizing solutions. Most use chlorine or iodine as the active ingredient. The Food Code provides some guidelines in using hand-sanitizing solutions. Sanitizing agents are regulated and must be used according to regulations and manufacturers recommendations. Typically, hand sanitizers are composed of chlorine compounds or iodine compounds intended for that purpose. According to the Food Code, a chemical hand sanitizing solution used as hand dip shall be maintained clean and at a strength equivalent to at least 100 ppm chlorine. Many processors will provide sanitizer hand dips to be used between hand washings. These hand dips may be in individual bowls at workstations or in faucets near workstations. Since some sanitizing agents dissipate

over time, they must be monitored often to ensure proper strength. Keep in mind that concentrated sanitizing solutions are considered to be toxic substances and must be properly stored.

Hand sanitizers should be checked with the appropriate test strips to ensure that the proper concentration is being used. Test strips specifically designed to measure the amount of iodine or chlorine sanitizer being used are readily available from manufacturers of these products. Misuse of hand sanitizers could actually cause problems by irritating employees' skin and causing infectious rashes or irritations. Processors should also be aware that sanitizing agents should be used under correct conditions. For example, a chlorine compound may dissipate over time and lose its effectiveness. Some chlorine compounds may be rendered ineffective when in the presence of organic matter such as in a crustacean peeling plant where hands are subject to a high organic load. Consequently, hand sanitizing hand dips should be changed frequently to insure that they are clean and maintained at the proper strength.

4-8. Recommendations for Hand Sanitizing Facilities:

- Proper sanitizer concentrations with strengths of 100-200 ppm chlorine, or 12.5-25 ppm iodine;
- Frequent monitoring and changes to maintain proper concentrations; and
- Conveniently located to encourage employee use but to avoid contact with foods.

Reference and Further Reading

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4-9.

Sanitation Control Guide

Entry date:	Hand Washing	FDA Key Condition No. 4

Concern: Proper maintenance of hand washing facilities and toilets

Examples:

Hand wash station lacks proper supplies and hot water. Hand sanitizer not available at the proper concentration or not properly maintained. Toilets not working properly or not cleaned.

Controls and Monitoring:

Check handwash and sanitation station for adequate supply of soap, towels, hot water and hand sanitizer.
Frequency: Daily, pre-op; water temperature weekly.

Check condition, operation and cleanliness of all toilets.
Frequency: Daily, pre-op.

Recommended Corrections:

Immediately provide necessary supplies. Make necessary adjustments in water temperature. Refill hand sanitizer containers and discard sanitizer if concentration is incorrect. Make up new hand dip sanitizing solution and verify correct concentration with test strips. Clean and repair all toilets before allowing employees to use and work in processing area.

Records:

Daily Sanitation Control Record

Chapter 5
Protection from Adulterants

Introduction

This chapter covers protection of food, food-packaging materials and food contact surfaces from various microbiological, chemical and physical contaminants, such as lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and floor splash. Seafood can be considered 'adulterated' if they become contaminated by such substances.

5-1. Key Sanitation Concern No. 5:

To ensure that the food, food-packaging material and food contact surfaces are protected from various microbiological, chemical and physical contaminants, such as lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and floor splash.

Any fishery product, component and/or ingredient is deemed to be adulterated if it meets the definition of an adulterated food under Section 402 of the Food Drug and Cosmetic Act and its related regulations under 21 CFR. While the legal definition is quite detailed, this chapter will focus on the parts of this legal definition that relate to sanitary practices. Interestingly, this definition requires scrutiny of sanitary practices because the adulterant 'may' be present due to improper sanitary practices. Foods processed in unsanitary conditions can be considered adulterated even without any evidence or measures of a contaminant.

5-2. Definition: Adulterated Food:

- If it (food) bears or contains any poisonous or deleterious substance which may render it injurious to health; . . .
- If it (food) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

Source: Section 402 of the Food, Drug and Cosmetic Act, items (a) 1 and (a) 4

The fishery product processor needs to be aware of all avenues which would cause a food product to be adulterated such that it may be unsafe to eat due to possible indirect or unforeseen contamination from such things as lubricants, fuel, pesticides, condensate, and residues or aerosols from toxic cleaning compounds. Plant employees must be trained to anticipate and recognize these possible indirect routes of contamination.

The possible causes are listed below.

Contamination from toxic compounds

1. Non-food grade lubricants in seafood products are considered adulterants because they may contain harmful substances.

2. Fuel contamination of seafood renders the product adulterated.

3. Only approved pesticides and rodenticides should be used to control pests in the plant and these compounds should only be applied as stated on the label.

4. Improper use of chemicals, cleaners, and sanitizers can cause adulteration of product directly through splash or spillage, or indirectly through aerosols and mist. Food, food contact surfaces and packaging materials should be removed, covered, or rinsed thoroughly when exposure to contaminants is possible.

5. Employees should be alert for toxic aerosols from non-food areas (outside the premises) or adjacent processing rooms.

Contamination from insanitary condensate or standing pools of water

1. Contaminated drips or condensate may contain pathogens, chemical residues, and filth that may render a product adulterated.

2. The lack of proper ventilation may cause condensation and drips to fall on the product, product contact surfaces and packaging materials.

3. Pooled or standing water could splash on the product or product contact surfaces, rendering the product adulterated. Splashing could be caused by foot or vehicle traffic through the standing water.

(Note: Condensation collecting on a sanitary surface (such as the clean, inside surface of a kettle lid) or in areas where product contact is highly unlikely (finished packaged product cooler) does not have to be addressed during the monitoring of this sanitation concern.)

Monitoring

The goal to monitoring this area is to ensure that the food, food-packaging material and food contact surfaces are protected from various microbiological, chemical and physical contaminants. As discussed in the next chapter (Chapter 6), the use of toxic compounds – pesticides, cleaning and sanitizing agents, fuel and lubricants – are frequently necessary in the seafood processing environment. In addition to these compounds, condensate forming on insanitary surfaces and water pooling on the floor are potential sources of microbial contamination of food products.

5-3. Goal:

To ensure that the food, food-packaging material and food contact surfaces are protected from various microbiological, chemical and physical contaminants.

When determining what to monitor, the seafood processor needs to be aware of how toxic compounds and condensate forming on insanitary surfaces and floor splash could potentially contaminate product. Processors must remember that contaminating product contact surfaces, ingredients and packaging materials is equivalent to contaminating the finished product.

5-4. What to monitor:

Any possible adulterant that could contaminate the food or food contact surfaces including:

- potential toxic compounds; and
- insanitary water (e.g., condensate forming on insanitary surfaces and standing pools of water).

A recommended monitoring frequency is at Pre-op or start-up and every four hours thereafter. The processor should be aware of the potential for product adulteration during the entire day's operation from pre-op through processing and sanitation activities. Proper corrections would need to be taken when deviations from the established sanitation practices are noticed.

5-5. When to monitor:

- With sufficient frequency to ensure conformance;
- Recommend at start-up and every four hours during work hours; and
- Observe conditions and activities throughout the day.

Corrections to any unsatisfactory activity which could result in product adulteration should be made in a timely fashion to prevent potential contamination of food, food contact surfaces or packaging materials. The following list outlines some possible corrections to inappropriate activities (5-6).

5-6. Possible Corrections:

- Remove condensate from insanitary surfaces;
- Correct air flow and room temperatures to reduce condensation;
- Install covers to prevent condensation from falling on food, packaging materials or food contact sufaces;
- "Squeegee" floor to remove standing water;
- Direct foot or vehicle traffic around pools of standing water;
- Wash food contact surfaces inadvertently exposed to chemical adulterants;
- Erect screens to protect product when working with a toxic compound in a non-product area;
- Evaluate impact of improper use of toxic compounds to assess whether or not food has been contaminated;
- Reinforce training of employees to correct inappropriate activities; and
- Discard unlabeled chemicals.

Records

The records used to document conformance to protecting food, food packaging material, and food contact surfaces from adulteration do not have to be complicated. The example Daily Sanitation Control Record (5-7) combines the monitoring activity for two key sanitation conditions. The general statements on the recording forms can be very inclusive and can appear redundant with other listed monitoring concerns for cleanliness and sanitation. The distinction is to prevent a substance from adulterating the food. More detailed explanations can be part of a written SSOP plan. Likewise, some firms may customize their Daily Sanitation Control Records to specify checks for particular areas or procedures in processing, i.e.,

- no accumulation of condensate on the ceiling;
- location of hand dips or sanitizers relative to food and immediate food contact surfaces to prevent contamination from splashing; and
- no wash waters and residue runoff near food and food packaging.

Background

Protection from adulteration can be considered a 3-step process – before, during and after processing. Protection from adulteration before processing is best accomplished with a written SSOP plan. This plan should describe the requirements for receipt, handling and storage of packaging material, dry food ingredients, and fishery products to ensure they are not adulterated with non-food grade lubricants, fuel, chemicals, pathogens, sanitizer residues, condensate, through insect or rodent infestation, condensate, drip, aerosols, sanitizer residues or other deleterious substances. This plan should be communicated to the suppliers of food products, ingredients and packaging materials. Also, preliminary considerations for plant design and operation can reduce concerns for adulteration. Operating conditions should consider personnel flow, equipment layout and design, product flow, and ventilation controls that could influence surface condensation, and water and waste disposal.

The same SSOP plan can detail the required monitoring procedures to prevent adulteration during processing. The FDA regulations for HACCP compliance require routine sanitation monitoring to prevent adulteration during the actual processing procedures. The monitoring records will demonstrate that practices are adequate to prevent and correct potential adulteration.

Finally, the processor can not be responsible for all possible sources and causes of adulteration after the product leaves the processing operation, but prior considerations could influence product adulteration after processing. Selection of packaging materials, package integrity, cleanliness of transport vehicles, and further handling instructions can prevent potential contamination from both biological (microbial and pests) and chemical adulteration by persons and conditions used in transport, storage, display and consumer use. For example, selection of packaging materials should consider potential exposure to adulterants, the packaging operation should be monitored for integrity and proper components (i.e., inks, glues, etc.) and handling instructions should be communicated to handlers and buyers through product labeling and/or prior agreements.

Condensation

Condensation is a common problem in seafood processing environments and can lead to adulteration. Condensation dripping onto products in food handling or storage areas must also be prevented or controlled. Seafood processing and handling frequently occurs in a “wet” environment and moisture can collect or condense on ceilings, walls, overhead fixtures, pipes, and condenser coils or refrigeration units in coolers. Any area where moisture collects can provide a good environment for spoilage bacteria and pathogens such as *Listeria monocytogenes* to grow and multiply. Cross contamination can occur when dripping water or condensate from the plant facility or equipment is allowed to drip or splash onto ready-to-eat products.

Food handling and storage areas should be routinely monitored to ensure that these products are not exposed to this type of contamination. Plant equipment or conditions that cause dripping or condensation should be fixed or corrected as soon as they are observed, and products and ingredients should be covered or otherwise protected from this type of contamination until repairs are completed. Drip pans or other devices used to collect condensation in coolers or other areas should be drained frequently and cleaned and sanitized regularly. Mishandling of hoses during production hours often results in splash from floors onto food contact surfaces.

Work and storage areas must also be kept clean and free of standing puddles of water that could splash onto products and contaminate them with bacteria. These conditions should be monitored both inside and outside the plant. Monitoring should include loading docks and receiving areas, storage areas and coolers, as well as food-handling and production areas.

5-7.

DAILY SANITATION CONTROL RECORD

Report Date: 10/22/99

Firm Name: Any Seafood Co., Inc.

Line 1: Raw Seafood (not ready-to-eat)
Line 2: Ready-to-eat

Firm Address: Anywhere, USA

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time: 6:00P	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hoses (S/U)	U					Replaced backflow prevention on hose faucet
2) Condition and Cleanliness of Food Contact Surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U)	S					
Line 2: (S/U)	S		S	S		
◆ Sanitizer Strength Sanitizer Type: Chlorine Strength: 100-200 ppm						
Line 1: (ppm)	100					Adjusted to 100 ppm before use (4:40 P)
Line 2: (ppm)	100		100	50		
◆ Gloves and aprons clean and in good repair Line 1: (S/U)		U				Replace 10 pairs of gloves (8:30 A)
Line 2: (S/U)		S				
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U)		S	S	U		Two staff told to change apron before changing work stations
◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U)			S	S		Raw fillets stored above & dripping onto boxed smoked fish. Product checked and re-packed.
◆ Unpackaged cooked products separated from raw products (S/U)			S	S	U	

5-7. (Continued)

Daily Sanitation Control Record (page 2)

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time:	Comments and Corrections
4) Maintenance of Hand-washing, Hand-sanitizing, and Toilet Facilities ◆ Hand-washing and hand-sanitizing stations adequate • Hand-washing station Line 1: (S/U)	S					
Line 2: (S/U)	S					
• Hand-sanitizing station Sanitizer Type: Iodine Strength: 12.5; 25; 24 (ppm) Line 2: (ppm)	25		25	25		Filled empty soap dispensers in men's bathroom
◆ Toilets clean, properly functioning, and adequately supplied (S/U)	U					
5) Protection from adulterants and 6) Labeling, Storage, and Use of Toxic Compounds ◆ Product protected from contamination (S/U)		S	U	S		Fan repositioned to prevent condensation on ceiling.
◆ Cleaning compounds, lubricants, and pesticides labeled and stored properly (S/U)						
7) Employee Health Conditions ◆ Employees do not show signs of medical problems (S/U)						
8) Exclusion of Pests ◆ Pests excluded from processing area (S/U)						

S = Satisfactory / U = Unsatisfactory

Signature or initials BSJ

5-8.

Sanitation Control Guide

Entry date:	Adulteration	FDA Key Condition No. 5

Concern: Adulteration of Food Products

Examples:
Pest strips hung over food packaging area. Non-food-grade lubricants used on equipment. Condensation falling from ceiling, rafters, pipes and cooling coils above food handling area can drip onto foods, packing materials and work surfaces causing contamination.

Controls and Monitoring:
Check the type, use and positioning of pest control devices relative to food processing and storage. **Frequency: Daily, pre-op.**

Routinely check that only food grade lubricants are used whenever moving machine parts are in contact with food. **Frequency: Daily, pre-op.**

Check for ceiling and structure condensation before and during processing. **Frequency: Daily, pre-op and every 4 hours.**

Recommended Corrections:
Remove or re-position pest control devices in non-food handling area. Replace non-food grade lubricants (e.g., motor oil) with approved lubricants and evaluate any exposed product. Correct air flow and room temperatures to reduce condensation. Consider insulation to reduce surface temperature differences that cause condensation. Provide covers to prevent any condensation from falling on foods, packaging or work surfaces. Swab condensate in a manner so as not to contaminate foods. Evaluate any exposed product.

Records:
Daily Sanitation Control Record

Chapter 6

Proper Labeling, Storage and Use of Toxic Compounds

Introduction

This chapter covers labeling, storage and use of toxic compounds. It is important to note that improper use of toxic compounds is a frequent cause of product adulteration.

6-1. Key Sanitation Condition No. 6:

Proper labeling, storage and use of potentially toxic compounds.

Chemicals used in most food processing plants include compounds such as cleaners, sanitizers, rodenticides, insecticides, machine lubricants and some food additives. Without them the facility cannot operate. But they must be used wisely and carefully. They must be used according to manufacturer's instructions, have proper labeling, and be stored in a safe manner; otherwise, they will pose a risk of contamination of the food products that the establishment is handling or manufacturing. All relevant government regulations relating to the application, use, or holding of these products should be followed. Due to the large number of different compounds available for use in facilities today, this chapter will not discuss specific information for each compound. Instead a general overview will be provided. Processors are encouraged to obtain additional information on compounds and solutions used in their processing operations.

Monitoring

6-2. Goal:

To ensure that the labeling, storage and use of toxic compounds are adequate to protect food from contamination.

The goal in monitoring this condition is to ensure that the labeling, storage and use of toxic compounds are adequate to protect food from contamination by toxic compounds. Areas of concern include food contact surfaces, packaging materials, and ingredients used both in processing and contained in finished products. Toxic compounds include cleaners, sanitizers, pesticides (for both insects and rodents), machine lubricants and other compounds needed to clean and maintain the seafood-processing environment.

When determining what to monitor, the seafood processor needs to consider the **proper storage, proper labeling**, as well as **proper usage** of toxic compounds.

6-3. 'What' to Monitor:

Are toxic compounds:
- properly labeled?
- properly stored?
- properly used?

The original containers for all chemicals must be labeled to show the name of the manufacturer, instructions for use, and the appropriate approvals (i.e., EPA registration). They should be enclosed in sanitary containers bearing the name and address of manufacturers or other qualifying phrases such as "manufactured for," "packed for," or "distributed by" if the substance is marketed by a firm other than the manufacturer. Often, it is necessary to take portions of the compound from the original container for use in the facility, since the original container is typically much too large and heavy for ease of use on the plant floor. Therefore, the working containers used for storing or using compounds such as cleaners and sanitizers which are routinely taken from the bulk supplies must also be clearly and individually identified with the common name of the material.

6-4. Proper Labeling of Containers:

- Original container labels should show:
  - Name of compound or solution in the container;
  - Name and address of manufacturers or "Manufactured for" or "Packed for" or "Distributed by" and appropriate approvals; and
  - Instructions for proper use.
- Working container labels must show:
  - Name of compound or solution in the container; and
  - Instructions for proper use.

Chemicals used in cleaning and sanitizing treatments, as well as pesticides and rodenticides, must be properly stored in an area of limited access away from food handling or manufacturing. Usually this means in a locked room or cage, with the keys or combinations given only to necessary personnel. Cleaning chemicals should be segregated from insecticides and rodenticides to prevent accidental mixing or misuse. Likewise, food-grade chemicals should be stored away from nonfood-grade compounds. Typically, the original containers of the compounds are sufficient and well designed for this specific purpose.

6-5. Proper Storage of Toxic Compounds:

- room with limited access;
- segregate food grade from non-food grade; and
- keep away from food equipment, utensils and other food contact items.

These chemicals of concern should not be stored above food, equipment, utensils, or packaging materials. Working containers used for storing these materials, such as cleaners and sanitizers, that have been taken from the bulk supplies must also be sanitary and cleanable. A container previously used to store poisonous or toxic materials must not be used to store, transport, or dispense food or food ingredients, and should also not be used to store cleaners and sanitizers that would come into contact with food-contact surfaces. Likewise, the working container for using cleaners and sanitizers must not be a food container which could inadvertently be used to pack a food product.

6-6. NEVER!

Containers used to hold cleaners and sanitizers must not be food containers that could inadvertently be used to pack a food product.

Only those chemicals that are necessary for the operation and maintenance of a food establishment should be allowed in the facility. The proper use and handling of these chemicals, including cleansers, and detergents, is necessary to reduce the possibility of cross-contamination, adulteration, and ultimately illness. Compounds must be used in accordance to the manufacturer's instructions or recommendations. All substances must be used in a manner that will not result in the adulteration of food products. Compounds must always be used according to applicable directions provided on the EPA registered label. The Material Safety Data Sheets (MSDS) supplied with the compound by the manufacturer or the supplier will provide information on its safe use.

6-7. Proper Use of Compounds:

- According to manufacturer's instructions; and
- Procedure will not result in adulteration of products.

The storage, use and labeling of toxic compounds should be monitored with sufficient frequency to ensure conformance with this sanitation condition and practice. A recommended monitoring frequency is at least once per day. A "pre-op" inspection may be appropriate to ensure chemicals used for the previous day's cleanup have been properly returned to storage. Processors should be continuously aware of the usage of toxic compounds during the entire day's operation - from pre-op through processing and sanitation activities.

6-8. 'When' to Monitor:

- with sufficient frequency to ensure conformance;
- recommend at least once per working day; and
- observe conditions and activities throughout the day.

Corrections

Corrections to an unsatisfactory activity involving toxic compounds should be made in a timely fashion to prevent potential contamination of food, ingredients, food contact surfaces or packaging materials. The following list outlines some possible corrections to inappropriate activities:

- move incorrectly stored toxic compounds to proper storage location;
- return compounds with inadequate labeling back to supplier;
- relabel working containers which incorrectly identify compounds contained within;
- destroy or discard inappropriate or damaged working containers;
- evaluate impact of improper use of toxic compounds to assess whether or not food has been contaminated (in some cases destruction of the food may be necessary); and
- reinforce training of employees to correct inappropriate activities.

6-9. Possible Corrections:

- move incorrectly stored toxic compounds;
- return to supplier if inadequately labeled;
- correct labeling;
- destroy damaged containers;
- assess safety of food; and
- reinforce training of employees.

Records

The records used to document conformance to the proper labeling, storage, and use of toxic compounds do not have to be complicated. Example 6-10 shows an excerpt from a sample "Daily Sanitation Control Record" which groups concerns for all possible adulterations with monitoring for potential adulteration from toxic compounds. Obviously, potential adulteration from toxic compounds deserves specific attention. The monitoring activity suggested by this form is for a designated plant employee to observe that cleaning compounds, lubricants, and pesticides are labeled and stored properly. This monitoring activity, which is conducted at pre-op, can be judged satisfactory or unsatisfactory. Obviously an unsatisfactory rating would require some corrections. Other types of documentation can be just as effective to show compliance with the regulation. Another type of record is a "log" which would contain multiple days of monitoring information on one form (see I-25 and I-26, Introduction). A log, posted by the chemical storeroom, would keep a running history of conformance to this sanitation concern.

Background

It is important that the following serve as a general discussion only and that more detailed information applicable to the specific compounds can be found on the label as well as with the material data safety sheets (MSDS) required with potential toxic substances.

Cleaners and Sanitizers

Food products and packaging materials must be removed from the room or carefully protected before using compounds such as general cleaning agents, compounds for use with steam or mechanical cleaning devices, acid cleaners, and floor and wall cleaners. After using these compounds, surfaces must be thoroughly rinsed with potable water. When using floor and wall cleaners in areas with subfreezing temperatures, potable water rinsing is not required following their use, provided the solution and the soil it contains are effectively removed by wiping or wet vacuuming.

Residues resulting from the use of scouring cleaners should be carefully removed from surfaces by thoroughly rinsing with potable water. Metal cleaners and polishes for nonfood contact surfaces should be used in a manner so that all odors associated with the compounds are dissipated before food products or packaging materials are exposed again in the area.

Before using degreasers or carbon removers for food cooking or smoking equipment and utensils, food products and packaging materials should be removed from the room or carefully protected. After using these compounds, surfaces must be thoroughly rinsed with potable water and the compounds should be used in a manner so that all odors are dissipated before food products or packaging materials are exposed in the area. Laundry detergents, bleaches, and scours may be used on fabric that contacts food products, directly or indirectly, provided that the fabric is thoroughly rinsed with potable water at the end of the laundering operation. Metal cleaners and polishes for nonfood contact surfaces and paint removers for use in nonprocessing areas should be handled similarly.

Compounds for use on all surfaces in inedible product processing areas, nonprocessing areas, and/or exterior areas must not be used to mask odors resulting from unsanitary conditions. They must be used in a manner that prevents penetration of any characteristic odor or fragrance into edible product areas. Compounds containing isomers of dichlorobenzene, or other substances toxic by inhalation, may be used only in areas where there is adequate ventilation to prevent accumulation of hazardous vapors.

Hand-washing compounds should be dispensed from adequate dispensers located a sufficient distance from the processing line to prevent accidental product contamination. Under conditions of use, there should be no odor or fragrance left on the hands. When using combination hand-washing and sanitizing compounds, the hands need not be washed prior to the use of the compounds. After the use of the compounds, the hands should also be thoroughly rinsed with potable water. When using hand-sanitizing compounds, the hands should be washed and thoroughly rinsed prior to sanitizing with the compound. The compound may be injected directly into the wash and rinse water and the hands need not be rinsed with potable water following the use of the compound. The use of hand creams and lotions should be limited to toilets and dressing rooms. Employees who handle edible products may use the lotions only when leaving the plant.

6-10. Daily sanitation monitoring form.

DAILY SANITATION CONTROL RECORD

Report Date: 10/22/99

Firm Name: Any Seafood Co., Inc.

Line 1: Raw Seafood (not ready-to-eat)
Line 2: Ready-to-eat

Firm Address: Anywhere, USA

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time: 6:00P	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hoses (S/U)	U					Replaced backflow prevention on hose faucet
2) Condition and Cleanliness of Food Contact Surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U)	S					
Line 2: (S/U)	S		S	S		
◆ Sanitizer Strength Sanitizer Type: Chlorine Strength: 100-200 ppm						
Line 1: (ppm)	100					Adjusted to 100 ppm before use (4:40 P)
Line 2: (ppm)	100		100	50		
◆ Gloves and aprons clean and in good repair Line 1: (S/U)		U				Replace 10 pairs of gloves (8:30 A)
Line 2: (S/U)		S				
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U)		S	S	U		Two staff told to change apron before changing work stations
◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U)			S	S		Raw fillets stored above & dripping onto boxed smoked fish. Product checked and re-packed.
◆ Unpackaged cooked products separated from raw products (S/U)			S	S	U	

6-10. (Continued)

Daily Sanitation Control Record (page 2)

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time:	Comments and Corrections
4) Maintenance of Hand-washing, Hand-sanitizing, and Toilet Facilities ◆ Hand-washing and hand-sanitizing stations adequate • Hand-washing station Line 1: (S/U)	S					
Line 2: (S/U)	S					
• Hand-sanitizing station Sanitizer Type: Iodine Strength: 12.5-25 ppm Line 2: (ppm)	25		25	25		Filled empty soap dispensers in men's bathroom
◆ Toilets clean, properly functioning, and adequately supplied (S/U)	U					
5) Protection from Adulterants and 6) Labeling, Storage, and Use of Toxic Compounds ◆ Product protected from contamination (S/U)		S	U	S		Fan repositioned to prevent condensation on ceiling. Unlabeled yellow liquid in chemical storage discarded.
◆ Cleaning compounds, lubricants, and pesticides labeled and stored properly (S/U)	U					
7) Employee Health Conditions ◆ Employees do not show signs of medical problems (S/U)						
8) Exclusion of Pests ◆ Pests excluded from processing area (S/U)						

S = Satisfactory / U = Unsatisfactory

Signature or initials BSJ

Water and Septic Tank Additives

Compounds used for water treatment should not remain in the water in concentrations greater than required by good practice. Chemical agents may be added to water used to cook and cool containers of food products to prevent staining of containers and to control corrosion and deposit formation on surfaces of processing equipment. The amount used should be the minimum sufficient for the purpose. Chemicals used as boiler water additives must meet the requirements specified in 21 CFR 173.301 – Boiler Water Additives.

Lubricants

Lubricants designed for incidental contact may be used on food processing equipment as a protective antirust film, as a release agent on gaskets or seals of tank closures, and as a lubricant for machine parts and equipment in locations in which there is potential exposure of the lubricated part to food. The amount used should be the minimum required to accomplish the desired technical effect on the equipment. If used as an antirust film, the compounds should be removed from the equipment surface, by washing or wiping, as required to leave the surface effectively free of any substance that could be transferred to food being processed. Lubricants designed for no contact may be used as a lubricant, release agent, or antirust film on equipment and machine parts or in closed systems (e.g., hydraulic systems) in locations in which there is no possibility of the lubricant or lubricated part contacting edible products.

Soluble oil products are chemically acceptable for application to hooks, trolleys, and similar equipment to clean and prevent rust. Those portions of the equipment that contact edible products must be made clean and free of the mixture before reuse.

If lubricants can contaminate food contact surfaces, they must meet the requirements specified in 21 CFR 178.3570 – Lubricants with Incidental Food Contact. These regulatory references can be confusing. For questionable substances, processors should seek advice from local authorities. The lubricant should be considered a potential contaminant if it is used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces.

Pesticides and Rodenticides

Residual pesticide compounds must be used in a manner that prevents their entry into edible product areas through open windows, ventilating systems, etc. Before using controlled fumigants, all edible products and packaging materials must be removed from the room to be fumigated. After fumigation, the treated equipment and space must be thoroughly aerated to remove all vapors before personnel reenter the area. Food contact surfaces must be rinsed with potable water before edible products are returned to the room.

Restricted use pesticides shall meet the requirements specified in 40 CFR 152 Subpart I – Classification of Pesticides. Rodent bait shall be contained in a covered, tamper-resistant bait station. A tracking powder pesticide should not be used in a food establishment. Only a nontoxic tracking powder such as talcum or flour that will not contaminate food, equipment, utensils, and packaging materials may be used.

Other Compounds

Absorbents or antislip agents for spot application to floors may be used in all areas provided that use is limited to the portion of the floor area where the danger of slipping exists, and that such use does not result in dusting, tracking, or other objectionable conditions. Compounds should not be used as a substitute for good sanitation. They must be removed as a part of the routine floor cleaning operation.

Following the use of cleaning and/or degreasing solvents in nonprocessing areas, equipment and utensils must be thoroughly washed and rinsed with potable water before being returned to a processing area. Before using solvents for cleaning electronic instruments, adhesives and glue removers, food products, and packaging materials must be removed from the area or carefully protected. These compounds must be used in a manner so that all odors associated with the compound are dissipated before food products or packaging materials are in the area.

First aid supplies that are in a food establishment for the employees' use shall be labeled and stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, and packaging materials. Only those medicines that are necessary for the health of employees shall be allowed in a food establishment. Medicines that are in a food establishment for the employees' use shall be labeled as such and located in a manner to prevent the contamination of food, equipment, utensils, and packaging materials.

Employees should store their personal care items in facilities designed and set aside specifically for such uses.

Reference and Further Reading

Current Good Manufacturing Practices, Part 110, Title 21, Code of Federal Regulations.

Food Code, U.S. Department of Health and Human Services, Public Health Services, Food and Drug Administration, Washington, D.C., 1999.

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products. Food and Drug Administration, Federal Register, Vol. 60, No. 242, December 18, 1995.

Rishoi, Don C. and Robert B. Gravani. Food Store Sanitation. Cornell University Distance Education Program, Ithaca, NY, 1986.

6-11.

Sanitation Control Guide

Entry date:	Toxic Compounds	FDA Key Condition No. 6

Concern: Proper Labeling, Storage, and Use of Toxic Compounds

Examples:

A chlorine-based sanitizer is being poured into a bottle labeled as detergent. A finished product tray is being used as a “drip catch pan” during the application of a lubricant. The contaminated tray could inadvertently be used for packaging a seafood product. An employee applying insecticide in a dry storage room is using a chemical insecticide that according to the manufacturer’s instruction is only intended for outside use. A pallet of detergent is stored on top of a pallet of breading.

Controls and Monitoring:

All chemicals, including those used for cleaning the restrooms and office areas, shall be stored in a closed and locked cage in dry storage away from food packaging materials. Only authorized quality assurance and maintenance personnel will have access to the cage. All chemicals purchased for use in the facility must either be labeled to show the name of the manufacturer, instructions for use, and the appropriate EPA approval or documentation provided with the necessary information. Smaller working containers, such as used for hand sanitizing compounds, will be filled by authorized quality assurance or maintenance personnel only. Such containers will be properly marked with the common name of the substance and will not be stored in any way that may cause the compound to fall or drip into food or onto food packaging materials. **Frequency: Daily, pre-op.**

Recommended Corrections:

Improperly labeled, stored, or used working containers will be corrected immediately. Food containers or packaging materials should not be used for storing or handling toxic compounds. Any chemical compound not having label instructions or document instructions for proper storage and use will be placed on hold until such documentation may be obtained. If such documentation cannot be obtained, the compound will be returned to the supplier. Leaking containers shall be resealed or replaced as necessary. Order of the storage cage will be corrected by the next working day. Any misuse of chemical compounds will result in corrections and retraining as determined necessary. If potential contamination of food product or food packaging material is present, the effected material or product will be removed from the area and discarded or destroyed as applicable. Employees found not adhering to the policy on personal care items and medicines will be retrained.

Records:

Daily Sanitation Control Record Employee Training Records

Chapter 7

Control of Employee Health Conditions

Introduction

This sanitation condition relates to persons who appear to have an illness, wound or other affliction that could be a source of microbial contamination of the food. It is imperative that managers prevent employees from working with foods or food contact surfaces when they are ill or have an infectious wound that has the potential to contaminate the product.

7-1. Key Sanitation Condition No. 7:

Manage persons who are diagnosed with or have symptoms of an illness, wounds or other afflictions that could be a source of microbial contamination.

Employee health and hygiene are major components of a firm's sanitation control program. Disease producing organisms can be spread by careless workers handling the food products. In some cases, individuals may be a carrier, which means the individual transmits the organism without actually exhibiting symptoms of the disease. Unless good hygienic habits are practiced, food handled by such a person can, in turn, transmit the disease to unsuspecting consumers.

Monitoring

7-2. Goal:

The primary goal of monitoring employee health is to control conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces.

Monitoring must be used to observe plant employees for symptoms of illness and for wounds that could potentially contaminate food. Before beginning plant operations, or at the start of each shift, observe employees for signs of illness or wound infections. Supervisors who routinely observe their employees soon become aware of visual clues that an employee may not be feeling well. If a supervisor suspects a problem, then it is prudent to talk with the employee.

7-3. Common Symptoms and Conditions to be Aware of in Processing Plant Employees:

- diarrhea;
- fever;
- vomiting;
- jaundice (yellow skin or eyes);
- sore throat with fever;
- open skin sores or cuts;
- boils; and
- dark urine.

Because a person's health status can literally change overnight, it is important to monitor employee health on a daily basis. As suggested previously, it is appropriate to do this before employees begin working. Therefore, this monitoring procedure is one of those that should be performed on a pre-op basis. Employees have responsibility under this sanitation condition. According to the FDA 1999 Food Code, employees must report if they have a diagnosed illness, a symptom or a high-risk condition.

Corrections

If an employee is determined to have symptoms of a disease, or infections that could contaminate food products, supervisors should:

1. Reassign and relocate an employee to a nonfood processing area or send the employee home until the questionable health condition has changed or tests are negative.

2. When lesions are present, an employee should be reassigned, sent home, or an impermeable cover must be placed over the lesions.

Records

The health of processing employees should be recorded daily on an appropriate section of a daily sanitation control record (7-4) before the start of production. All unsatisfactory conditions must be recorded with an accompanying correction taken to reduce or eliminate the problem.

7-4.

DAILY SANITATION CONTROL RECORD

Report Date: 10/22/99

Firm Name: Any Seafood Co., Inc.

Line 1: Raw Seafood (not ready-to-eat)
Line 2: Ready-to-eat

Firm Address: Anywhere, USA

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time: 6:00P	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hoses (S/U)	U					Replaced backflow prevention on hose faucet
2) Condition and Cleanliness of Food Contact Surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U)	S					
Line 2: (S/U)	S		S	S		
◆ Sanitizer Strength Sanitizer Type: Chlorine Strength: 100-200 ppm						
Line 1: (ppm)	100					Adjusted to 100 ppm before use (4:40 P)
Line 2: (ppm)	100		100	50		
◆ Gloves and aprons clean and in good repair Line 1: (S/U)		U				Replace 10 pairs of gloves (8:30 A)
Line 2: (S/U)		S				
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U)		S	S	U		Two staff told to change apron before changing work stations
◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U)			S	S		Raw fillets stored above & dripping onto boxed smoked fish. Product checked and re-packed.
◆ Unpackaged cooked products separated from raw products (S/U)			S	S	U	

7-4. (Continued)

Daily Sanitation Control Record (page 2)

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time:	Comments and Corrections
4) Maintenance of Hand-washing, Hand-sanitizing, and Toilet Facilities ◆ Hand-washing and hand-sanitizing stations adequate • Hand-washing station Line 1: (S/U)	S					
Line 2: (S/U)	S					
• Hand-sanitizing station Sanitizer Type: Iodine Strength: 12.5-25 ppm Line 2: (ppm)	25		25	25		Filled empty soap dispensers in men's bathroom
◆ Toilets clean, properly functioning, and adequately supplied (S/U)	U					
5) Protection from Adulterants and 6) Labeling, Storage, and Use of Toxic Compounds ◆ Product protected from contamination (S/U)		S	U	S		Fan redisposi-tioned to prevent condensation on ceiling.
◆ Cleaning compounds, lubricants, and pesticides labeled and stored properly (S/U)	U					Unlabeled yellow liquid in chemical storage discarded.
7) Employee Health Conditions ◆ Employees do not show signs of medical problems (S/U)	U					Fillet packer with cut hand moved to front office.
8) Exclusion of Pests ◆ Pests excluded from processing area (S/U)						

S = Satisfactory / U = Unsatisfactory

Signature or initials BSJ

Background

A review of contributing factors in U.S. foodborne disease outbreaks over a five-year period (1988 - 1992) by the Centers for Disease Control and Prevention (CDC) revealed that poor personal hygiene was implicated in more than one third of the cases. The CDC has identified the infectious and communicable diseases that can be transmitted through food by infected employees. CDC updates the list annually (http://www.cdc.gov/).

Some pathogens are frequently transmitted by food contaminated by infected persons. The presence of any one of the following signs or symptoms in persons who handle food may indicate infection by a pathogen that could be transmitted to others through handling of the food supply: diarrhea, vomiting, open skin sores, boils, fever, dark urine, or jaundice. However, as mentioned earlier, it is also important to realize that employees may be carriers of certain pathogens (i.e., *Salmonella typhi, Shigella* spp., and *E. coli* O157:H7) without exhibiting any symptoms. The failure of food-handlers to wash hands (in situations such as after using the toilet, handling raw meat, cleaning spills, or carrying garbage, for example), wear clean gloves, or use clean utensils is responsible for the foodborne transmission of these pathogens. Non-foodborne routes of transmission, such as from one person to another, are also major contributors in the spread of these pathogens.

A food worker diagnosed with an active case of illness like *Salmonella typhi, Shigella* spp., *Escherichia coli* O157:H7, and Hepatitis A caused by any of these pathogens must be excluded or restricted from the food handling areas. The medical consequences of infection with these pathogens can be severe requiring hospitalization and in some cases resulting in death. If contaminated products are sold to highly susceptible populations such as the elderly, infants and small children, and persons with immunodeficiency disease, a case of foodborne illness could have more serious medical consequences beyond the mild flu-like symptoms a healthy person experiences.

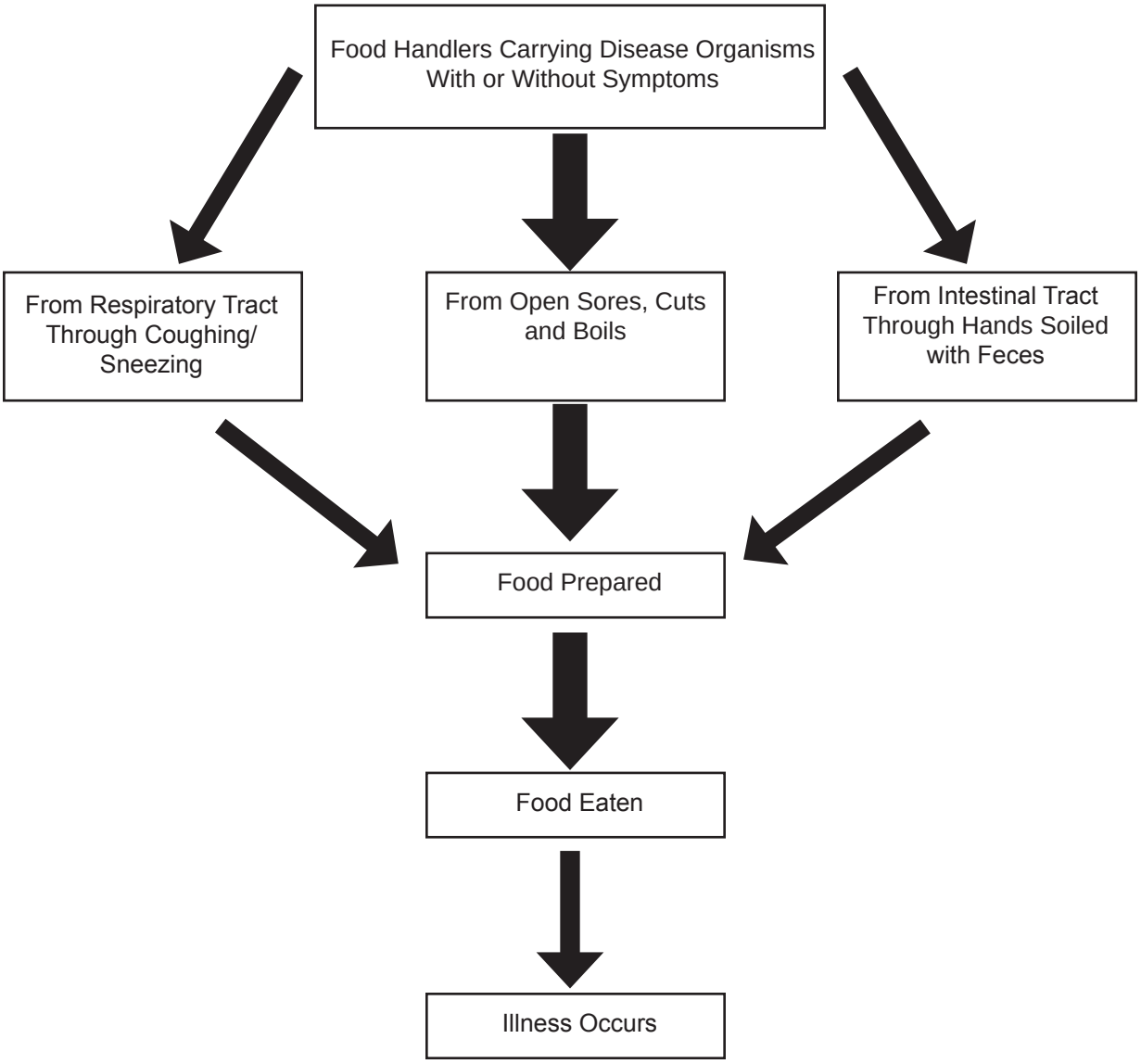
7-5. Pathogen and illness that can be transmitted by food contaminated by infected employees.

Pathogen	Diarrhea	Fever	Vomiting	Jaundice	Sore Throat with Fever
Hepatitis A virus		✓		✓	
Salmonella typhi		✓			
Shigella spp	✓	✓	✓		
Norwalk and Norwalk-like viruses	✓	✓	✓		
Staphylococcus aureus	✓		✓		
Streptococcus pyogenes		✓			✓
Campylobacter jejuni	✓	✓	✓		
Entamoebea histolytica	✓	✓			
Enterohemorrhagic *E. coli*	✓				
Enterotoxigenic *E. coli*	✓		✓		
Giardia lamblia	✓				
Nontyphoidal *Salmonella*	✓	✓	✓		
Rotavirus	✓	✓	✓		
Taenia solium					
Vibrio cholerae	✓		✓		
Yersinia enterocolitica	✓	✓	✓		

Source: (CDC, 9/22/97, Diseases Transmitted Through the Food Supply and FDA/CFSAN the 'Bad Bug Book' and FDA 1999 Food Code.)

The diagram below shows the route of transmission from the food handler, whether they are ill or a carrier of disease-causing organisms, to the food, which is then eaten by customers. If employees are a carrier their health history should be evaluated and used to make decisions about their assignments in the food plant.

7-6. Route of Disease Originating From Food Handler



Management Responsibilities

The federal GMP state that "plant management shall take all reasonable measures and precautions to ensure that no adverse employee health conditions exist that could lead to contamination of product, packaging, or food contact surfaces" (Appendix). To ensure good hygiene for the food handlers, management should consider the following:

- The health of the employees; special attention should be given to diarrhea, fever, vomiting, jaundice and upper respiratory complaints because these symptoms can spread bacteria and viruses. Employees with open lesions should not be considered for work involving food or food contact surfaces until the cuts or wounds are completely healed. The use of bandages or gloves to cover hand infections is not always sufficient protection to allow resumption of work in the food processing area.

- A clear understanding with the employees that they will not *lose* their employment if they report they have contracted an illness or communicable disease.

- A posted pictorial, in addition to established company policy, for the employee which indicates how personal health is an essential part of good personal hygiene.

- An emphasis on the maintenance of a high level of cleanliness and good health.

- A regular surveillance of all food handlers for signs of diarrhea, fever, vomiting, jaundice and any evidence of poor personal hygiene.

- A written health policy that requires reporting, work restrictions and exclusions for employees that have symptoms of illness or high risk conditions.

7.7 Management responsibilities concerning employee health:

- Set company policy - when to restrict or exclude an ill employee and when to allow such an employee to return to work;
- Set company policy - health and personal hygiene;
- Provide a good example;
- Monitor employees;
- Provide proper design and maintenance of facilities, and
- Provide training.

Personnel Responsibilities

The food handler should assure personal hygiene by:

- Reporting any illness to your supervisor before you undertake work with food so that work adjustments can be made to protect the public from the food handler's illness. Your supervisor understands how pathogens can be spread in a processing facility and can make a decision about what location and job in the plant is best for you until your health allows you to resume your previous duties.

- Keeping in a good state of health by the use of proper rest, nutrition, exercise, and physical cleanliness. If exposed to pathogens that cause foodborne illness, a person in good physical health has a greater chance of fighting off infections than does a person in poor health. In turn, good health reduces the chance for transmitting microorganisms in the plant.

- Being health conscious and conscientious in the protection of your health. If you are conscientious about the protection of your own health, it means you are being conscientious about other peoples health and you can feel good about the food your company produces.

- Practicing good personal hygiene through daily bathing; use of appropriate deodorants; and proper hair cover and care. These are the steps you need to take for good physical cleanliness.

- Hair in food can be a source of both microbiological and physical contamination. To prevent hair from contaminating food, appropriate hair covers should be worn. This would include wearing hairnets for both men and women, even under hats, and over beards. It is important that hairnets cover all areas of hair. All personnel in a processing area should wear hats. This includes employees, plant managers, and visitors. Hair should be washed at least once a week or more frequently as needed.

- Keeping nails clean and trimmed. As part of a good personal hygiene program you are minimizing the chance for dirt/soil including food particles from accumulating under your nails. Trimming your nails also makes it easier for you to do a good job washing your hands.

- Avoiding practices such as sneezing, coughing, etc. that could contaminate food.

- Observing the no smoking, no eating and drinking rules in food preparation and service areas.

7-8. Personnel Responsibilities:

- Maintain good health;
- Report illness;
- Wash hands after sneezing, coughing, scratching, etc.; and
- Be aware of conditions that might cause contamination.

7-9.

Sanitation Control Guide

Entry date:	Employee Health	FDA Key Condition No. 7

Concern: Monitoring and Management of Employee Health Conditions

Examples:

New employee health is in question. Employee appears to be suffering from a symptom such as diarrhea, fever, vomiting, jaundice or sore throat with fever. Employee has a lesion containing pus, such as a boil or infected wound that is open or draining on hands or wrists, exposed portion of arms, or on other parts of body. Employee is not experiencing a symptom of acute gastroenteritis, but testing reveals a specimen culture that is positive for *Salmonella typhi*, *Shigella spp*. or *Escherichia coli* 0157:H7.

Controls and Monitoring:

Management should observe general employee health, including infected wounds before the start of operations for each shift. **Frequency: Daily, pre-op.**

Recommended Corrections:

Do not employ persons with chronic illnesses to do jobs that could contaminate the foods being processed. Reassign or send home until tests are negative. Exclude employee, with illness or infection that could contaminate foods, from all food processing areas, or reassign to a nonfood processing area, or cover lesion with an impermeable cover.

Records:

Pre-employee agreement indicating health before hire, willingness to take training and abide by guidelines for reporting to supervisor when ill or having been exposed to a confirmed outbreak.

Employee Management and Training records. Daily Sanitation Control Record.

Chapter 8

Exclusion of Pests

Introduction

This chapter relates to the presence of pests, such as rodents, birds, and insects. The presence of rodents, birds, insects, or other pests in the processing plant is unacceptable. Even if pest control is contracted to an outside company, it is still the processor's responsibility to make sure that there are no pests in the facility.

8-1. Key Sanitation Condition No. 8:

No pests in the food processing plant.

When discussing pests, many people visualize rodents as the primary culprit, but in reality pests take on many forms in a food processing facility. These include birds; numerous species of flying and crawling insects such as cockroaches, flies, grain beetles, and moths; as well as dogs, cats, raccoons, and various rodents. The impact of pests in the food industry is heavy in monetary terms with the loss of billions of dollars worldwide. While this monetary loss is important, the overriding concern is that food safety will be compromised by pests in food-processing facilities. The presence of pests in a food plant can result in illness to consumers through microbial contamination. Even if the pests do not cause illness, filth such as insect parts, rodent hair and droppings can be distressing for consumers when they discover it in their food.

8-2. Foodborne illnesses that may be passed on by pests are numerous:

- Flies and cockroaches may transmit *Salmonella, Staphylococcus, C. perfringens, C. botulinum, Shigella, Streptococcus*, and others;
- Rodents are sources for *Salmonella* and parasites; and
- Birds are hosts for a variety of pathogens such as *Salmonella* and *Listeria.*

Monitoring

The eighth key sanitary condition is primarily concerned with "pests in the plant," while the related Good Manufacturing Practices (GMP) address all attributes of pest control. Required monitoring involves a visual inspection for both the **presence of pests** (for example, domestic animals, insects, rodents and birds), and for current or recent **evidence of pests**, such as droppings, gnaw marks and nesting material. Typically, monitoring includes observations in the processing, packing and storage areas. To be successful, it should also involve monitoring other related conditions which, if not controlled, could lead to pest problems.

8-3. Goal:

Monitoring must confirm that pests are excluded from relevant areas of the plant to the extent possible and should also confirm that procedures are followed to prevent infestation.

8-4. Monitoring for exclusion of pests:

- Visually inspect for presence of pests in processing areas;
- Use flashlight to expose potential hiding places and to check traps; and
- Maintain good housekeeping to facilitate inspections.

Monitoring frequency will vary depending on what is monitored. Inspection of the physical facility for possible entry points may be a periodic function, perhaps weekly or even monthly. The monitoring for direct evidence of pests in the plant is specifically required by the FDA HACCP regulation and should normally be performed 'daily.' Experience may demonstrate the need to monitor more or less frequently. Example monitoring schedules are shown in the example form (8-6) and in the sanitation control guides.

Corrections

When a facility's monitoring program reveals sanitation-related deficiencies that may introduce a food safety hazard or perhaps impact the wholesomeness of a food product, the facility is required to correct the problem. The presence of pests is a sanitation discrepancy that must be resolved appropriately when identified. The background section of this chapter provides details that should help in establishing criteria for determining other conditions requiring correction. The appropriate solution is often dependent on the situation. Complex or even simple pest problems may require some thought prior to implementing a final solution. For example, in the case of flies in a processing area, a predetermined correction for the short term may be to exterminate existing flies and clean waste handling

areas near the plant. A longer-term solution may require installation of air curtains and moving waste storage facilities to an area away from the plant entrance.

8-5. Corrections

Example

Observation: After pesticide and trap use, flies re-enter processing areas

Correction: Add air curtain above outside door and move waste storage container away from door

Records

As with each of the eight sanitation conditions, the observations related to exclusion of pests made while monitoring must be documented and these records must be available if requested during an FDA inspection. Evidence of corrections is a required part of this record. Records provide evidence that the company's sanitation program is adequate, that it is followed and that problems are identified and corrected. The example record 8-6 identifies a daily checkpoint in one of numerous possible formats for recording observations. Notice that, in this example, the record only addresses the minimum requirement that pests be excluded from processing areas. As previously indicated, additional monitoring is normally necessary to ensure the exclusion of pests. A record that documents this additional monitoring may identify successful or unsuccessful control strategies, and provide a very useful management tool. It is recommended but is not required.

8-6.

DAILY SANITATION CONTROL RECORD

Report Date: 10/22/99

Firm Name: AnySeafood Co., Inc.

Firm Address: Anywhere, USA

Line 1: Raw Seafood (not ready-to-eat)
Line 2: Ready-to-eat

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time: 6:00P	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hoses (S/U)	U					Replaced backflow prevention on hose faucet
2) Condition and Cleanliness of Food Contact Surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U)	S					
Line 2: (S/U)	S		S	S		
◆ Sanitizer Strength Sanitizer Type: Chlorine Strength: 100-200 ppm						
Line 1: (ppm)	100					
Line 2: (ppm)	100		100	50		Adjusted to 100 ppm before use (4:40 P)
◆ Gloves and aprons clean and in good repair Line 1: (S/U)		U				Replace 10 pairs of gloves (8:30 A)
Line 2: (S/U)		S				
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U)		S	S	U		Two staff told to change apron before changing work stations
◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U)			S	S		Raw fillets stored above & dripping onto boxed smoked fish. Product checked and re-packed.
◆ Unpackaged cooked products separated from raw products (S/U)			S	S	U	

8-6. (Continued)

Daily Sanitation Control Record (page 2)

Sanitation Area and Goal	Pre-Op Time: 7:35A	Start Time: 8:10A	4 Hour Time: 12:15	8 Hour Time: 4:26P	Post-Op Time:	Comments and Corrections
4) Maintenance of Hand-washing, Hand-sanitizing, and Toilet Facilities ◆ Hand-washing and hand-sanitizing stations adequate • Hand-washing station Line 1: (S/U)	S					
Line 2: (S/U)	S					
• Hand-sanitizing station Sanitizer Type: Iodine Strength: 12.5-25 ppm Line 2: (ppm)	25		25	25		Filled empty soap dispensers in men's bathroom
◆ Toilets clean, properly functioning, and adequately supplied (S/U)	U					
5) Protection from Adulterants and 6) Labeling, Storage, and Use of Toxic Compounds ◆ Product protected from contamination (S/U)		S	U	S		Fan repositioned to prevent condensation on ceiling.
◆ Cleaning compounds, lubricants, and pesticides labeled and stored properly (S/U)	U					Unlabeled yellow liquid in chemical storage discarded.
7) Employee Health Conditions ◆ Employees do not show signs of medical problems (S/U)	U					Fillet packer with cut hand moved to front office.
8) Exclusion of Pests ◆ Pests excluded from processing area (S/U)	U					Flies killed and new door curtains installed.

S = Satisfactory / U = Unsatisfactory

Signature or initials BSJ

Background

Controlling pests in a food processing facility is essential in order to minimize the transmission of foodborne illnesses caused by microbial contamination. Generally, pest control is a three-phase procedure.

8-7. Three phase pest control program:

1. Elimination of shelter and attractants;
2. Exclusion of pests from the food plant; and
3. Extermination of those pests that gain entry.

First a company should perform an initial inspection of their facility in order to understand their present ability to address these three areas of concern and to assess what must be accomplished to eliminate deficiencies that may present a potential food safety hazard. The facility should then establish a standard to be maintained in order to demonstrate that measures are in place to exclude pests from the food plant, e.g., "windows and doors are tightly sealed to prevent entry of pests."

In establishing an exclusionary program for pest control in a food processing facility, there are a number of areas of concern. Some of these are, but are not limited to: plant and grounds; structure and layout; plant machinery; equipment and utensils; housekeeping; waste disposal; and the use of pesticides and other control measures. An initial pest control audit or checklist is provided to help perform an initial assessment of the potential pest problems. Such detailed documentation is useful but is not required by the federal HACCP regulation.

8-8. Complete Pest Exclusion Program:

<u>Required Monitoring</u>

1. Presence / Absence of Pests.

<u>Related Conditions</u>

1. Plant and Grounds;
2. Structure and Layout;
3. Plant Machinery, Equipment and Utensils;
4. Housekeeping;
5. Waste Disposal; and
6. Use of Pesticides and other Control Measures.

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8-9. **Example Pest Control Checklist (not required): Plant and Grounds**

1. Are the grounds clear of weeds, tall grass, brush, and debris to minimize cover for pests to approach and enter the facility?
2. Is there standing water on the grounds which may attract pests?
3. Are traps sufficient in number, well maintained and in good repair?
4. Are there signs of the presence of domestic animals or large feral animals (including but not limited to dogs, cats or raccoons)?

As previously mentioned, well-kept and maintained grounds inhibit rodents and many other pests from approaching and entering a processing facility. In addition, it is important to assess the possibility that neighboring properties may be potential sources of pests. A simple solution may be to communicate with your neighbor the need to maintain the grounds along your property line. Another exclusionary practice is to establish a system of bait traps or other suitable control along the property's perimeter.

Exterior inspections should include assurances that the grounds are clear of tall weeds, grass, brush, and debris which may encourage pests to approach and potentially enter the facility. Rodents and most pests do not feel secure in open spaces, preferring the security offered by clutter or tall unkempt plants.

Inspections should also include identification of potential roosting or nesting areas for birds; a common source of human pathogens. Look especially for bird activity near air intakes, which may draw airborne microorganisms into the plant. Because birds on the roof will contaminate rainwater, make sure it is guttered and directed away from product-handling areas, employee entrances or any area that could cause soil to be tracked into the plant.

Keep in mind that a number of solutions are available that may fit a particular situation. Rodents, insects and birds are not the only concerns. It is quite possible that local pets and domestic animals may pose a problem. Observe for any droppings or other signs. A pet may be abandoned and become feral in an effort to survive. It may establish a habitat on the facility grounds. Such situations often require the assistance of the local animal control officer.

Despite every effort to maintain the plant grounds, pests will inevitably try to gain entry and, in many cases, succeed. It is important to assess the facility's capacity for excluding pests. This assessment is simply an observation of the plant to determine its physical capability to exclude pests. As you walk along the outside of the plant note whether doors and windows are closed and sealed properly, and if they have screening which is intact and of a sufficient mesh size to prevent the entry of pests.

Ensure that drainage systems are clear and cleaned properly; that there are no blockages to prevent proper drainage or to allow for harborage or entry of pests. Drain blockages may sustain pests such as cockroaches or flies. It is also important to ensure that drain covers are clean and in good repair. Keep in mind that you are not only concerned with drains and drain covers outside the facility but those

inside the plant. Should the outside drain covers fail, it may be the drain covers on the other end of the system that prevent pests from gaining entry.

Rodents and most other pests do not require a large opening to gain entry. A mouse can enter an opening as small as ¼-inch in diameter and a rat an opening ½-inch square. Note any openings, cracks or crevices ¼ inch or greater. Any noted openings should be filled with a suitable material, such as steel wool or caulking to prevent potential entry. On occasion, it is helpful to observe from inside the facility, under subdued lighting conditions, for areas of daylight that may indicate an opening sufficient in size to allow for the entry of pests. This includes windows, doors and walls bordering the outside physical plant.

8-10. Example Pest Control Checklist Continued for:

Building / Facility

5. Do windows and doors seal tightly to prevent entry of pests or contaminants?
6. Do windows have screens in good repair to keep out insects?
7. Are there openings of 1/4-inch or greater that will allow entry of rodents and insects?
8. Are drains properly cleaned and free of buildup that may act as an attractant to rodents and other pests?
9. Is there sufficient clearance space (six-inch minimum between walls and equipment) to inhibit rodent activity?
10. Are drain covers in good repair and properly fitted?

The control of pests inside the processing facility is affected by other elements of the sanitation program. The failure of a facility to maintain a proper cleaning and sanitizing program may allow for the buildup of protein residues and other static materials that act as attractants to pests (refer to Chapter 2 – Food Contact Surfaces). Another concern is the design and layout of the processing facility. Proper design and layout is essential in ensuring that there is sufficient spacing to allow cleaning and sanitizing personnel to thoroughly clean and sanitize process equipment and machinery. There should not be any “dead spaces” which may allow for the buildup or collection of food or other debris; serving as an attractant or harborage for pests.

Specialized devices are often used to control pests in processing plants, such as blacklight electrocution devices and air curtains. Care should be taken to ensure that these devices are properly installed and routinely maintained in accordance with the manufacturer’s recommendations. If blacklight devices are installed too high off of the floor or if the blacklight light intensity levels are too weak they will not attract flying insects. Some blacklight devices are designed to prevent debris from being thrown away from the device. Others may not be so designed, resulting in contamination of the product if installed too close to processing areas. Catch basins of the devices must be cleaned out routinely to prevent overflow that may again contaminate the product or food contact surfaces. Air curtains must be installed at a particular height and position within design specifications in order to perform to standard. If improperly specified or installed, they are likely to be ineffective and may actually force insects into the plant.

8-11. Example Pest Control Checklist Continued for:
Plant Machinery, Equipment and Utensils

11. Are machinery, equipment and utensils properly cleaned and sanitized to eliminate the build-up of food or other static materials that may act as an attractant to pests?
12. Is there sufficient space along the process line to allow for proper cleaning and sanitizing?
13. Are there any "dead spaces" which may allow for the build-up or collection of food and other debris acting as attractant or harborage of insects and bacteria?
14. Are blacklight units maintaining the proper light intensity levels to attract flying insects?
15. Are blacklight electrocution devices properly set up?
16. Are the blacklight electrocution device catch basins cleaned out regularly?

Thorough and efficient housekeeping practices can significantly reduces pest problems. If proper housekeeping standards are not maintained, the resulting buildup of trash, debris and clutter is likely to attract rodents and other pests. These pests may actually take up residence among the trash, debris and clutter. When the pests take up residence, it creates a difficult extermination problem. In addition, personnel lockers or breakrooms that are not well maintained will likely attract a variety of pests. It is common for employees who store or "forget" food products in lockers or fail to maintain a clean breakroom to discover they are supporting unwanted guests such as cockroaches or mice. It is also helpful, as general standard operating procedure, to ensure personnel are trained to readily recognize indicators of the presence of pests and to understand procedures for reporting any observations when noted. For example, do they recognize droppings, hair, urine/ammonia odors, gnaw marks or grease runs from rodent activity? Are there signs of egg casings or bore holes from insects? Are there indications of feathers, droppings or nesting of birds? When noted, any indication of pest entry or presence should be cleaned up and the area observed in order to determine the continued presence or the level of activity of the particular pest.

8-12. Example Pest Control Checklist Continued for:
Housekeeping

17. Is trash, debris and clutter picked up eliminating cover for pests?
18. Are personnel locker rooms and break rooms cleaned and sanitized to inhibit the attractions of rodents and other pests?
19. Are there signs of rodent, insect, or bird habitation, e.g., droppings, hair, feathers, gnaw marks, grease runs from rodent activity along walls, urine/ammonia odors?
20. Have previously noted indicators of pest habitation been cleaned up in order to note any new or continued activity?

If not properly collected, stored and disposed of "gurry" or waste material may act as an attractant to rodents and other pests. Any spills or overflows should be cleaned up as soon as possible. To prevent cross-contamination of food products and to minimize the potential attraction and support of rodents and other pests, storage areas for waste materials require nearly as much attention to detail when cleaning and sanitizing as do processing areas. In addition to the storage area, waste bins, tubs and dumpsters used in the collection, holding and storage of waste materials require proper cleaning and sanitizing to minimize the potential attraction and support of food pests.

8-13. Example Pest Control Checklist Continued for: <u>Waste Disposal</u>

21. Is waste material properly collected, stored and disposed of in order to inhibit the attraction of rodents and other pests?
22. Are waste bins, tubs and/or dumpsters properly cleaned and sanitized in order to inhibit the attraction of rodents and other pests?

The majority of process facilities will contract with an outside pest control service as a tool to control pests as a component of a sanitation program. It is important to remember that it is the processing facility's responsibility to maintain and implement a program to exclude pests. Plant management must be aware at all times of which pest control practices and procedures are in place, what and how various pesticides, rodenticides and other chemicals are used, if they are appropriate, and how successful they are. The processor and service provider should maintain open and regular communication. The effectiveness of any pest management program, including contracted work, must be monitored and documented. Such documentation must indicate that problems are identified and properly resolved.

Authorized Use of Pesticides

Awareness of the regulatory requirements relating to the authorized use and handling of chemicals and poisons used in the control of pests is very important. Through the **Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Environmental Pesticide Control Act (FEPCA)**, the Environmental Protection Agency (EPA) has the responsibility for the regulation of pesticides related to their registration, labeling, manufacture, transportation and use in the United States.

The use of pesticides may be separated into two categories:

8-14. Categories of Pesticide Use:

1. General use insecticides; and
2. Restricted use insecticides.

"General use insecticides" are those that will not ordinarily have an adverse effect on either the user or the environment when properly used. "Restricted use insecticides" are those that may have an

adverse effect on the user or environment through exposure, unless applied under controlled conditions by or under the supervision of a trained, certified person. The FEPCA provides for two levels of certification; private applicators and commercial applicators.

8-15. Certification of Applicators:

1. Private applicator; and
2. Commercial applicator.

A private applicator is an applicator who is certified to use restricted use insecticides in the production of an agricultural commodity on property owned or rented by him or his employer. A commercial applicator is any person who applies a restricted use insecticide beyond the definition of "private applicator." An example might be a government or state employee, health department agent, or a commercial pest control operator. Certification of private applicators may be accomplished through either a written or oral examination, but commercial applicators must be identified through the use of a written examination, and in some instances with the support of performance testing. Contact local authorities such as county extension offices for information on examination schedules.

8-16. General Standards for Applicator Certification:

1. Label and labeling comprehension;
2. Safety;
3. Environmental factors and the consequence of use and misuse of the pesticide;
4. Knowledge of pests; and
5. Knowledge of pesticides and types of formulations, including the hazards associated with residues.

The FEPCA is specific in citing civil and criminal penalties for the misuse or abuse of a pesticide inconsistent with the manufacturer's instruction. Civil penalties are a maximum fine of $5,000 and criminal penalties up to $25,000 and up to a year in jail for commercial applicators in violation of the law.

Sources of Additional Information

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4. *Household and Stored-Food Insects of Public Health Importance and Their Control, Harry D. Pratt, Kent S. Littig and Harold George Scott, US Dept of Health Education and Welfare, PHS, Center for Disease Control, Atlanta, Georgia, Revised 1975, HEW Publication No. (CDC) 77-8122*

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10. *Food Service Sanitation Manual, 1976, US Dept of Health, Education and Welfare, PHS, FDA DHEW Publication No. (FDA) 78-2081*

11. *Do Your own Establishment Inspection - A Guide to Self Inspection for the Smaller Food Proces sor and Warehouse, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, Industries Activities Section, 1994, Available on the Internet address: http://vm.cfsan.fda.gov/~dms/*

8-17.

Sanitation Control Guide

Entry date:	Grounds	FDA Key Condition No. 8

Concern: Exclusion of pests from the process facility

Examples:

Improperly stored equipment outside the plant, piled against the walls of the plant, hinders cleaning of the grounds or trash removal. Litter and waste materials accumulate on facility grounds as an attractant and/or harborage of pests. Waste disposal area unkempt, container doors open or overflowing, act as an attractant and/or harborage of pests. Grass, brush and weeds uncut around the facility act as an attractant and/or harborage of pests. Traps are not sufficient in number, maintained or in good repair. Standing water is present, acting as an attractant and/or harborage of pests.

Controls and Monitoring:

Regularly inspect the outside perimeter of the facility and remove or organize equipment, machinery or materials so as to minimize or not attract pests. **Frequency: Weekly**

Regularly inspect the grounds for accumulating litter and waste materials, and remove as noted. **Frequency: Weekly**

Inspect outside storage areas, ensuring that all stored materials are properly stored and secured as to prevent access or attraction of pests. As noted, remove any excess or prolonged unnecessary stored materials. As needed, repair damage and/or wear of facility plant. **Frequency: Daily for status; Weekly for repairs and verification of pickup/removal services.**

Cut and maintain the grass, brush and weeds to prevent/minimize the attraction/harborage of pests **Frequency: Weekly as needed.**

Inspect traps to ensure they are properly spaced, adequate in number, in good repair and effective. **Frequency: Daily.**

Maintain and repair grounds to prevent the development of areas of standing water. **Frequency: Weekly.**

Recommended Corrections:

Remove or properly store equipment and materials. Remove and properly dispose of all collected litter and waste materials. Implement repair and maintenance actions to plant and grounds in a timely manner. Cut grass, brush and weeds as required. Add additional bait traps and repair traps as needed, properly dispose of pests as they are noted and communicate with the pest control service.

Records:

Daily Sanitation Control Record

8-18.

Sanitation Control Guide

Entry date:	Plant Machinery, Equipment and Utensils	FDA Key Condition No. 8

Concern: Exclusion of pests from the food plant

Examples:

Machinery, equipment and utensils are not properly cleaned and sanitized to eliminate the buildup of food or other static materials that may attract rodents or other pests. There is insufficient spacing along the process line to allow for proper cleaning and sanitizing. There are “dead spaces” which allow for the buildup/collection of food or process debris that may act as an attractant or harborage of rodents or other pests. Blacklight electrocution devices are improperly installed, or are placed and operated at an intensity insufficient to attract flying insects.

Controls and Monitoring:

Regularly inspect the process line to ensure that all equipment, machinery and utensils are properly cleaned and sanitized. **Frequency: Daily (pre-op).**

Regularly inspect the process line to ensure there is sufficient spacing to allow for proper cleaning and sanitizing. **Frequency: Daily (pre-op).**

Inspect for “dead spaces” along the process line. **Frequency: Weekly.**

Ensure proper installation, placement and maintenance of blacklight electrocution devices. **Frequency: Upon installation, monthly thereafter.**

Verify the intensity of blacklight electrocution device light systems. **Frequency: Once every six months.**

Recommended Corrections:

If necessary, stop the process, tag the affected area and reclean and resanitize as necessary. Affected product should be re-evaluated before release. If necessary reorganize the processing line to ensure proper spacing sufficient to allow for proper cleaning and sanitizing. Identify and remove all “dead space,” if possible. If removal is not possible, implement an increased level of surveillance of the affected area sufficient to maintain control. Replace any failing or out-of-date blacklight electrocution device bulbs.

Records:

Daily Sanitation Control Record

8-19.

Sanitation Control Guide

Entry date:	Structure and Layout	FDA Key Condition No. 8

Concern: Exclusion of pests from the food plant

Examples:
Windows/doors are properly sealed and in good repair to prevent entry of pests and contaminants. Windows have a fine mesh screening in good repair installed. There are no openings 1/4 inches or more to allow for the entry of rodents or other pests. There are no domestic or feral animals present on the grounds. Drains are properly cleaned and free of buildup that may act as an attractant of rodents and/or other pests. Drain covers are clean, in good repair and fit properly. There is sufficient clearance space (six-inch minimum) to inhibit rodent activity.

Controls and Monitoring:

Regularly inspect facility, windows/doors to ensure proper seal when closed. **Frequency: Weekly.**

Regularly inspect window screening to ensure they are in good repair. **Frequency: Weekly**.

Regularly inspect plant structure (to include, but not limited to, walls, ceilings, floors, foundation, and doors) for holes, cracks and other openings sufficient in size (1/4 inch) to allow rodent entry. **Frequency: Weekly**

Regularly observe for signs or the physical presence of domestic or feral animals. **Frequency: Daily.**

Regularly inspect drains to ensure that they are cleaned, sanitized and in good repair, and inspect to ensure that the drain cover is clean, in good repair and fits snugly. **Frequency: Weekly for drains and daily for drain covers.**

Inspect storage and process areas to ensure there is at least six inches above the floor. **Frequency: Weekly.**

Recommended Corrections:
Repair window/door seals and screening as deficiency is noted. Fill/repair all noted openings (with steel wool, caulking material or other acceptable means) as openings are noted. Notify the local animal control officer to properly remove any domestic or feral animals noted. If necessary stop and tag the affected process line, contact the maintenance department or authorized professional service to repair affected drains, re-evaluate and release. Clean out or remove any improperly stored equipment, utensils or materials interfering with the maintenance of the six-inch clearance space.

Records:
Weekly and Monthly Sanitation Control Record

8-20.

Sanitation Control Guide

Entry date:	Waste Disposal	FDA Key Condition No. 8

Concern: Exclusion of pests from the food plant

Examples:

Waste materials are properly collected, stored and disposed of to preclude the attraction of rodents, insects (crawling and flying) and other pests. Waste collection containers (dumpsters, barrels, and cans) are properly cleaned and sanitized to preclude the attraction of rodents and other pests. Waste collection areas are properly cleaned and sanitized to preclude the attraction of rodents and other pests.

Controls and Monitoring:

Regularly observe the collection, storage and disposal process of waste materials. **Frequency: Daily.**

Regularly inspect waste containers to ensure they are properly cleaned and sanitized and regularly observe the cleaning and sanitation process for waste containers. **Frequency: Daily.**

Regularly inspect waste collection areas to ensure they are properly cleaned and sanitized. **Frequency: Daily.**

Recommended Corrections:

If necessary stop the process, properly collect, store and dispose of waste materials. If necessary stop the process, tag deficient containers, properly clean and sanitize, re-evaluate, and release. If necessary, stop the process, tag the effected area, clean and sanitize. If necessary retrain personnel and review procedures.

Records:

Daily Sanitation Control Record
Employee training

Example

SSOP Plan and Sanitation Control Records

Introduction

As mentioned in the introductory chapter, a complete food safety program includes both HACCP and accompanying sanitation control procedures. Similar to documenting procedures in a HACCP plan, sanitation standard operating procedures (SSOP) outline how a firm will maintain sanitary control within the plant.

Although a written SSOP plan is not required by the FDA, it is recommended to explain the in-plant procedures the firm will follow to control, monitor and correct the key sanitation conditions and practices covered in the previous chapter of this manual. SSOP plans are recommended because they:

- describe the sanitary procedures to be used in the plant;
- provide the schedule for the sanitation procedures;
- provide a training tool for employees;
- identify trends and prevent re-occurring problems;
- ensure that everyone, from management to production workers, understands acceptable sanitation practices;
- provide the foundation to support a routine monitoring program;
- encourage prior planning to ensure that corrrections are taken when necessary;
- demonstrate commitment to buyers and inspectors; and
- lead to improved sanitary practices and conditions in the plant.

Like HACCP plans, SSOP should be specific to each plant. SSOP should describe the plant's procedures associated with sanitary handling of food and the cleanliness of the plant environment and the activities conducted to meet them. Plants can choose to develop **informal** or **formal** SSOP plans. **Informal** SSOP may simply outline the frequency and procedures to be followed to control, monitor and correct deficiencies for a specific task or sanitation concern. The Model SSOP Plan on the following pages illustrates an informal SSOP. **Formal** SSOP are written to follow a standard format, so each SSOP is developed to contain standard information. Prior to developing a **formal** SSOP plan, firms would design a standard format to use for each individual SSOP. The standard format may include some or all of the following sections:

- purpose or objective of the SSOP;
- scope or relevance of the SSOP (e.g., preparation of hand dip stations in RTE product packing room);
- responsibility (e.g., the individual or job description responsible for implementing and/or monitoring the procedures in the SSOP);
- materials and equipment (e.g., listing any special tools or equipment needed to carry out the task and/or monitoring activity);
- procedures (documentation of the procedures necessary to carry out the SSOP);
- frequencies (how often the procedure in the SSOP will be used);
- documentation of changes (records why changes were made to SSOP and documents version numbers so the most recent version is being used); and
- approval section (e.g., signatures of acceptance by plant management).

There is no right or wrong way to write an SSOP, the important point to remember is that the SSOP should be easy to use and follow. An SSOP plan that is not followed will not be beneficial to the firm. The two most important aspects of any type of SSOP -- either informal or formal -- is that: 1) enough detail is provided for someone to carry out the task in question, and 2) the procedures listed accurately reflect the activities that are being conducted. An SSOP with too much detail may be counter-productive because strict adherence to the procedures may be difficult to achieve every time and it is likely to be informally modified over time. Likewise, an SSOP without enough detailed information will not be useful for a plant because the user will need to "fill in the blanks" to figure out how to complete a task.

If a company chooses to develop an SSOP plan, it will support the required sanitation control monitoring, record keeping, and correction activities. However, some firms may find the prospect of writing an SSOP plan to be overwhelming, even though the SSOP plan will prove to be very worthwhile in the long run. An easy way to start writing SSOP is to think through each sanitation operation that is being conducted in the plant and document how it is conducted, where it is being conducted, and who is responsible for conducting the operation. In addition, think through how the sanitation control procedure will be monitored, recorded and corrected if there is a deviation. Simply writing down the sanitation procedures that are currently being conducted in the plant is the first step to developing an SSOP plan.

The following example is one approach that can be used to develop an SSOP plan and accompanying sanitation control records. As explained in all previous chapters, proper monitoring for sanitary conditions and practices requires employee training and understanding of the appropriate procedures. The details necessary for training are usually too lengthy and could be redundant for placement on the sanitation monitoring forms. Brief descriptions of the monitoring requirements help to reduce the amount of paper involved and serve as simple reminders for the actual sanitation monitoring procedures.

Sanitation Standard Operating Procedures (SSOP) Plan

The model SSOP Plan in Table 1 addresses the sanitation concerns for a fictional seafood company processing a cooked ready-to-eat seafood product. The SSOP sections are based on the eight FDA key sanitation conditions. This information could be further explained and strengthened by Sanitation Control Guides as provided with each previous chapter. Although the approaches may differ, sanitation procedures, monitoring requirements, and necessary corrections all emphasize the importance of a written SSOP plan to support and explain the monitoring requirements and necessary corrections.

SSOP plans will vary from facility to facility because each facility and process is designed differently. This SSOP plan is for illustrative purposes and does not constitute a recommendation by the Seafood HACCP Alliance. The use of trade names does not constitute endorsement by the Seafood HACCP Alliance for any specific product.

Developing Sanitation Control Records

Monitoring forms for Sanitation Control Records are generated from the written SSOP plan. These monitoring control forms provide records for each FDA key sanitation condition. The "Daily Sanitation Records" (Table 2) and the "Periodic Sanitation Records" (Table 3) are based on the SSOP plan in Table 1. Outline numbers and letters in the monitoring forms correspond to specific sections of the SSOP plan.

Table 1. Model SSOP Plan

Sanitation Standard Operating Procedure

1. Safety of Processing Water and Ice (FDA Key Sanitation Condition No. 1)

Controls and Monitoring:

a. All water used in the plant is from a reliable municipal water system. Municipal water bills indicate that the water source is safe. **Monitoring Frequency: Annually.**

b. The water system in the plant was designed and installed by a licensed plumbing contractor, and meets current community building codes. All modifications to the plumbing system will be completed by a licensed plumbing contractor and will be inspected to ensure conformance with local building codes. Copies of building inspection reports indicate that the plumbing system is properly constructed. **Frequency: When plumbing is installed or modified.**

c. All water faucets and fixtures inside and outside the plant have antisiphoning devices installed. Water faucets and fixtures are inspected for the presence of antisiphoning devices. **Monitoring Frequency: Daily before processing.**

Corrections:

a. In the event of municipal water treatment failure, the plant will stop production, determine when the failure occurred, and hold products produced during the failure until product safety can be assured. Production will resume only when water meets state and federal water quality standards.

b. Corrections will be made to the plumbing system, if necessary, to correct problems. Production will resume only when water meets state and federal water quality standards.

c. Water faucets and fixtures without antisiphoning devices will not be used until antisiphoning devices have been installed.

Records:

a. Municipal water bill and periodic sanitation record.

b. Building plumbing inspection report and periodic sanitation record.

c. Daily Sanitation Control Record

2. Condition and Cleanliness of Food Contact Surfaces, Including Utensils, Gloves, and Outer Garments (FDA Key Sanitation Condition No. 2)

Controls and Monitoring:

a. Food contact surfaces are adequately cleanable (do not have cracks, cavities, crevices, overlapping joints, mineral scale, etc. that are not possible to adequately clean and sanitize). The sanitation supervisor inspects food-contact surfaces to determine if they are adequately cleanable. **Monitoring Frequency: Daily**

b. Food-contact surfaces are cleaned and sanitized:

1) Before operations begin, food-contact surfaces are rinsed with cold water and sanitized with a 100 ppm sodium hypochlorite sanitizer. The sanitation supervisor inspects food-contact surfaces to determine if they are sanitized. **Monitoring Frequency: Before operations begin.**

2) During breaks, major solids are physically removed from floors, equipment, and food-contact surfaces. All surfaces are rinsed with cold water. Equipment and food-contact surfaces are scrubbed using brushes with a chlorinated alkaline cleaner in warm (120°F) water. All surfaces and floors are rinsed with cold water. Check sanitizers and food contact surfaces. Food-contact surfaces are sanitized with a 100 ppm sodium hypochlorite sanitizer solution. Floors are sanitized with a 400 ppm quaternary ammonium chloride sanitizer. Utensils are cleaned in a deep sink with a chlorinated alkaline cleaner, rinsed in hot water (190°F), soaked in a 100-ppm sodium hypochlorite sanitizer for at least 10 minutes, and rinsed in hot water (190°F) prior to use. The sanitation supervisor checks sanitizers before use and inspects food-contact surfaces to determine if they are clean and sanitized. **Monitoring Frequency: At the 4 and 8-hour breaks.**

3) At the end of daily operations, major solids are physically removed from floors, equipment, and food-contact surfaces. Equipment is disassembled as required for adequate cleaning. All surfaces are rinsed with cold water. Equipment and food-contact surfaces are scrubbed using brushes with a chlorinated alkaline cleaner in warm (120°F) water. All surfaces and floors are rinsed with cold water. Floors and walls are sprayed with a 400 ppm quaternary ammonium chloride sanitizer solution. Utensils are cleaned in a deep sink with a chlorinated alkaline cleaner in warm (120°F) water, rinsed in hot water (190°F), soaked in a 100 ppm sodium hypochlorite sanitizer for at least 10 minutes, and air dried. The sanitation supervisor inspects food-contact surfaces to determine if they are clean and sanitized. **Monitoring Frequency: At the end of operations.**

c. Workers wear clean gloves and outer garments.

1) Workers working with raw and cooked product wear clean gloves, clean outer garments, waterproof aprons, and waterproof boots. Waterproof aprons are cleaned and sanitized twice each day, at the midday break and at the end of the shift.

2) Administrative personnel wear smocks and waterproof boots when in processing areas. Smocks are laundered in-house as needed.

3) Maintenance workers wear gray uniforms and waterproof boots. Uniforms are laundered in-house as needed.

4) Production supervisors monitor the use of gloves and the cleanliness of workers' outer garments. **Monitoring Frequency: Before operations and after each break.**

Corrections:

a. Food-contact surfaces that are not adequately cleanable are repaired or replaced.

b. Adjust sanitizer concentration. Food-contact surfaces that are not clean are cleaned and sanitized.

c. Gloves that become a potential source of contamination are cleaned and sanitized or replaced. Outer garments that become a potential source of contamination are cleaned and sanitized or replaced.

Records:

a-c. Daily Sanitation Control Record

3. Prevention of Cross-Contamination (FDA Key Sanitation Condition No. 3)

Controls and Monitoring:

a. Production supervisors have received basic food sanitation training. Plant manager schedules basic food sanitation courses for new production supervisors. **Monitoring Frequency: When production supervisors are hired.**

b. Employee practices do not result in food contamination (hair restraints, glove use, hand washing, personal belonging storage, eating and drinking, boot sanitizing).

1) Workers wear hairnets, headbands, caps, beard covers, or other effective hair restraints and do not wear jewelry or other objects that might fall into the product, equipment, or containers.

2) Workers wear disposable gloves and replace them as needed.

3) Workers wash their hands and gloves thoroughly and sanitize them before starting work, after each absence from their workstation, and anytime they have become soiled or contaminated.

4) Clothing and personal belongings are not stored in production areas.

5) Workers do not eat food, chew gum, drink beverages, or use tobacco in production areas.

6) Workers wear color-coded aprons (blue in raw product areas and white in cooked product areas) and are not allowed to enter or pass through other processing areas.

7) Workers sanitize their boots in boot baths containing 800-ppm quaternary ammonium chloride sanitizer solution before entering processing areas.

8) Production supervisors monitor employee practices. **Monitoring Frequency: Before operations and every four hours during production.**

c. Boot sanitizing solutions are checked every four hours during production. Sanitation supervisor checks boot sanitizing solutions. **Monitoring Frequency: Before operations and every four hours during production.**

d. Plant grounds are in a condition that protects against contamination of food. Sanitation supervisor inspects plant grounds. **Monitoring Frequency: Daily before operations.**

e. Waste is removed from processing areas during production. Sanitation supervisor monitors removal of waste. **Monitoring Frequency: Every 4 hours.**

f. Floors are sloped to facilitate drainage. Processing area floors are inspected for adequate drainage. **Monitoring Frequency: Daily before operations.**

g. Plant buildings are maintained in good repair. Raw-product processing and cooked-product processing areas are separated. Coolers, including the evaporators, are cleaned annually, or more often if needed. Nonfood-contact surfaces in processing and packaging areas are cleaned daily at the end of the shift. Raw and cooked products are physically separated in coolers. Packaging materials are protected from contamination during storage. Sanitation supervisor inspects plant. **Monitoring Frequency: Daily before operations.**

h. Cleaning and sanitizing equipment is color-coded for specific plant areas: blue for raw-product processing areas, white for cooked-product processing areas, and yellow for toilet facilities and general plant cleaning. Sanitation supervisor observes that proper equipment is used. **Monitoring Frequency: At each cleanup period.**

Corrections:

a. New production supervisors receive basic sanitation instruction.

b. Workers correct deficiencies in hair restraint use, jewelry use, glove use, hand washing, personal belonging storage, eating and drinking in processing areas, and boot sanitizing before working with raw or cooked products.

c. Boot sanitizing solution is changed.

d. Sanitation supervisor initiates correction of potentially contaminating condition.

e. Waste is removed

f. Floors with standing water will have the drains unplugged, or, if necessary, consultations will be held with plumbing or general contractors and corrections will be made to correct floor drainage problems.

g. Sanitation supervisor initiates correction of potentially contaminating condition including assessment of product quality.

h. Sanitation equipment that is being used in the wrong plant area is cleaned and sanitized and exchanged for correct equipment. Sanitation supervisor initiates correction of potentially contaminating condition.

Records:

a. Periodic Sanitation Control Record or training record

b-h. Daily Sanitation Control Record

4. Hand Washing/Sanitizing, and Toilet Facilities (FDA Key Sanitation Condition No. 4)

Controls and Monitoring:

a. Toilet facilities are provided off the workers' dressing room, physically separated from processing areas. Toilet facilities have self-closing doors, are maintained in good repair, and are cleaned and sanitized daily at the end of operations. Sanitation supervisor inspects the toilet facilities and hand washing facilities. **Monitoring Frequency: Daily before operations and every 4 hours during operations.**

b. Handwashing/sanitizing facilities are provided in raw and cooked processing areas and in the toilet facility. Hand washing facilities have: hot and cold running water with foot activated valves; liquid sanitizing hand soap; hand sanitizer solutions that are changed every 4 hours during production; sanitary towel service; signs directing workers to wash their hands and gloves thoroughly. Hands should be washed and sanitized before starting work, after each absence from their workstation, and anytime they have become soiled or contaminated. Sanitation supervisor inspects the hand washing facilities and checks hand sanitizer strength. **Monitoring Frequency: Daily before operations and every 4 hours during operations**.

Corrections:

a. Sanitation supervisor initiates cleaning of dirty toilet facilities and correction of any potentially contaminating condition. Repairs are made as needed.

b. Sanitation supervisor restocks facilities or adjusts sanitizers.

Records:

a-b. Daily Sanitation Control Record

5. Protection of Food, Food-Packaging Material, and Food-Contact Surfaces from Adulteration (FDA Key Sanitation Condition No. 5)

Controls and Monitoring:

a. Cleaning compounds, sanitizers, and lubricants used in processing and packaging areas are approved for use in food plants. Receiving manager checks invoices at receiving before food-grade chemicals are stored. **Monitoring Frequency: When cleaning compounds, sanitizers, and lubricants are received.**

b. Food-grade and non-food-grade chemicals and lubricants are stored separately outside processing and packaging areas. Sanitation supervisor inspects chemical storage areas. **Monitoring Frequency: Daily before operations.**

c. Food, food-packaging materials and food-contact surfaces are protected from adulteration from biological, chemical and physical contaminants. Safety-type light fixtures are used in processing and packaging areas. Sanitation supervisor inspects processing and packaging areas. **Monitoring Frequency: Daily before operations and every 4 hours.**

d. Equipment is in good repair with no loose or missing metal parts. Sanitation supervisor inspects processing and packaging equipment. **Monitoring Frequency: Daily before operations.**

e. Drip or condensate does not contaminate food or packaging materials. **Monitoring Frequency: Pre-op and at 4 and 8-hour breaks.**

Corrections:

a. Unapproved chemicals are returned or used in non-processing areas.

b. Improperly stored chemicals are moved to the correct storage area.

c. Safety of the product is examined.

d. Repairs are made as needed.

e. Sanitation supervisor corrects any condensation problems.

Records:

a. Periodic Sanitation Control Record

b-c. Daily Sanitation Control Record

6. Labeling, Storage, and Use of Toxic Compounds (FDA Key Sanitation Condition No. 6)

Controls and Monitoring:

a. All toxic compounds used in the plant are labeled with the manufacturer's name, use instructions, and the appropriate EPA approval, or have documentation with the necessary information. Receiving manager verifies that this information is present before toxic compounds are stored. **Monitoring Frequency: When toxic compounds are received.**

b. Cleaning compounds, sanitizing agents, lubricants, pesticide chemicals, and other toxic compounds are properly labeled and stored in a closed and locked cage in dry storage outside processing and packaging areas and separately from food-grade chemical, food-grade lubricant, and packaging material storage. Only authorized personnel have access to the cage. Sanitation supervisor checks cage for cleanliness and container leakage. **Monitoring Frequency: Daily before operations.**

c. All manufacturers' instructions and recommendations are followed. Only authorized personnel fill small working containers, such as containers of hand sanitizing compounds. These containers are properly marked with the common name of the chemical and are not stored in any way that may cause the chemical to fall or drip onto food or food-packaging materials. Sanitation supervisor verifies proper procedures and labeling. **Monitoring Frequency: Daily before operations.**

Corrections:

a. Toxic compounds without proper information are placed on hold until information is obtained. Toxic compounds without documentation are returned to the supplier.

b. Improperly stored chemicals are moved to the correct storage area. Leaking containers are resealed or replaced as necessary. Storage cage will be cleaned by the next working day.

c. Misuse of toxic compounds results in disciplinary action or retraining. Potentially contaminated food is discarded or destroyed. Improper labeling of working containers is corrected.

Records:

a. Periodic Sanitation Control Record

b-c. Daily Sanitation Control Record

7. Employee Health (FDA Key Sanitation Condition No. 7)

Controls and Monitoring:

a. Workers report to their immediate supervisor any health condition that might result in food contamination. Supervisors report suspected health problems to the plant manager. The plant manager decides if a potential food contamination situation exists. **Monitoring Frequency: Daily before operations.**

b. Supervisors check for infected lesions that might contaminate food. **Monitoring Frequency: Daily before operations.**

Corrections:

a. Workers who represent a potential risk are sent home or reassigned to non-food-contact jobs.

b. Cover lesion with impermeable bandage, reassign, or send worker home.

Records:

a-b. Daily Sanitation Control Record

8. Pests (FDA Key Sanitation Condition No. 8)

Controls and Monitoring:

a. A pest management firm treats the outside of the building. They also inspect the interior of the building and treat as necessary with appropriate chemicals. **Monitoring Frequency: Every other month.**

b. Plant grounds and interior areas are kept free of litter, waste, and other conditions that might attract pests. Outer plant doors are kept closed, processing areas are screened with plastic curtains, and electric bug-killing devices are located outside entrances to processing areas. No pets are allowed in the plant. Supervisors report any pest problems to the plant manager. The sanitation supervisor inspects for the presence of pests. **Monitoring Frequency: Daily before operations.**

Corrections:

a. Conditions that may cause pest problems are corrected.

b. The pest management firm is notified of any pest problem and treats the problem. Pest treatments are more frequent if problems are identified.

Records:

a. Periodic Sanitation Control Record

b. Daily Sanitation Control Record

Table 2.

Daily Sanitation Control Record	Date:			
Firm:	Mark S/U			
Address:				
Products being processed: (?)	Pre-Op	4-Hour	8-Hour	Post-Op
Condition	Time:	Time:	Time:	Time:
1. Safety of Water and Ice:				
c. Water faucets and fixtures have anti-siphoning devices.				
2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments:				
a. Equipment and utensils are adequately cleanable.				
b. Sanitation strength (ppm)/food contact surfaces and utensils are clean and sanitized.				
c. Gloves/garments contacting food are clean and sanitary.				
3. Prevention of cross-contamination:				
b. Employee practices do not result in food contamination (hair restraints, glove use, hand washing, personal belonging storage, eating and drinking, boot sanitizing).				
c. Boot sanitizer strength is adequate (ppm).				
d. Plant grounds are in good condition.				
e. Waste is removed from processing areas.				
f. Floors have adequate drainage.				
g. Plant buildings in good repair.				
Raw and cooked-product processing areas separated.				
No drip over food or packaging materials.				
Safety-type lighting used.				
Coolers and evaporators are clean.				
Non-food-contact surfaces are clean.				
Cooked and raw products physically separated in coolers.				
Packaging materials protected from contaminants.				
h. Proper color-coded sanitation equipment is used.				

Table 2. (Continued)

Daily Sanitation Control Record	Date:			
Firm:	Mark S/U			
Address:				
Products being processed: (?)	Pre-Op	4-Hour	8-Hour	Post-Op
Condition	Time:	Time:	Time:	Time:
4. Hand Washing Sanitizing, and Toilet Facilities:				
a. Toilets facilities are clean, sanitary and in good repair.				
b. Hand sanitizer strength (ppm)/hand washing and sanitizing supplies.				
5. Adulteration:				
b. Food-grade chemicals identified and stored properly.				
c. Food, food-packaging materials and food-contact surfaces are protected from adulteration.				
d. Equipment is in good repair.				
e. Drip and surface condensate.				
6. Toxic compounds:				
b. Toxic compounds identified and stored properly.				
c. Proper containers and procedures are used.				
7. Employee Health:				
a. Employee health conditions are acceptable.				
b. Employees do not have infected lesions.				
8. Pests:				
No pests in plant.				
Comments & Corrections:				
Report by:				
S = Satisfactory / U = Unsatisfactory				

Table 3.

Periodic Sanitation Control Record			Date:
Firm Name: **Firm Address:**			
Condition	**S**	**U**	**Comments/Corrections**
1. Safety of Water and Ice:			
a. Municipal water bill (annually).			
b. Building plumbing inspection report (when plumbing is modified).			
3. Prevention of cross-contamination:			
a. Production supervisors have received basic food sanitation training (when hired).			**Name(s):**
5. Adulteration:			
a. Invoices for food-grade chemicals checked before chemicals are stored (when received).			
6. Toxic compounds:			
a. Labels or documents for toxic compounds checked before compounds stored (when received).			
8. Pests:			
a. Pest management firm's report is satisfactory (every other month).			
Comments and Corrections:			
Report by: S = Satisfactory / U = Unsatisfactory			

Table 4. Chemicals Approved for Use in Plant

Chemical	Strength	Dilution
Chlorinated Alkaline Cleaner Brand: Clean-Up Now Usage: Equipment, food-contact surfaces, utensils, toilet facilities		1/4 cup concentrate to 6 gallons water (26 mL concentrate to 10 L water)
Liquid Sanitizing Hand Soap Brand: L-Sanitizer Usage: Hand washing facilities		Undiluted
Sodium Hypochlorite Sanitizer Brand: Hypo-Sanitizer Usage: Food contact surfaces	100 ppm	1/4 cup concentrate to 13 gallons water (12 mL concentrate to 10 L water)
Quaternary Ammonium Sanitizer Brand: QA-Sanitizer Usage: Floors Usage: Boot sanitizing baths	400 ppm 800 ppm	1/4 cup concentrate to 4 gallons water (39 mL concentrate to 10 L water) 1/4 cup concentrate to 2 gallons water (7.75 mL concentrate to 10 L water)
Iodine Sanitizer Brand: I-Sanitizer Usage: Hand sanitizing solutions	25 ppm	1/4 cup concentrate to 26 gallons water (6 mL concentrate to 10 L water)
Lubricants Brand: Wizard Grease Usage: Food processing equipment Brand: White Grease Usage: Non-food processing areas		

Revised: 3/17/99
Reviewed by (Plant Manager): _____ Date: _____

SSOP Record

1. Municipal water bills are reviewed and kept on file for two years.
2. Building plumbing inspection reports are reviewed and kept on file for two years.
3. Daily and Periodic Sanitation Reports are reviewed and kept on file for two years.
4. Invoices for food-grade chemicals and lubricants are reviewed and kept on file for two years.

Appendix A
Seafood HACCP Regulation

Title 21 of the Code of Federal Regulations Part 123 - Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule (Dec. 18, 1995)

Subpart A—General Provisions

§ Sec. 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

(a)Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b)Critical control point means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.

(c)Critical limit means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

(d)Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e)Fishery product means any human food product in which fish is a characterizing ingredient.

(f) Food safety hazard means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(g)Importer means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(h)Molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i)Preventive measure means physical, chemical, or other factors that can be used to control an identified food safety hazard.

(j)Process-monitoring instrument means an instrument or device used to indicate conditions during processing at a critical control point.

(k)Processing means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different marketforms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.
(2)The regulations in this part do not apply to:
(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
(ii)Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.
(iii)The operation of a retail establishment.

(l)Processor means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processing includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m)Scombroid toxin-forming species means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

(n)Shall is used to state mandatory requirements.

(o)Shellfish control authority means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p)Shellstock means raw, in-shell molluscan shellfish.

(q)Should is used to state recommended or advisory procedures or to identify recommended equipment.

(r) Shucked shellfish means molluscan shellfish that have one or both shells removed.

(s)Smoked or smoke-flavored fishery products means the finished food prepared by:
(1)Treating fish with salt (sodium chloride), and
(2)Subjecting it to the direct action of smoke from burning wood, sawdust, or similar

material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t)Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

§ Sec. 123.5 Current good manufacturing practice.

(a)Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

(b)The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

§ Sec. 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan.

(a)Hazard analysis. Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b)The HACCP plan. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1)Each location where fish and fishery products are processed by that processor; and

(2)Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods to gether, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c)The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1)List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii)Microbiological contamination;

(iii)Chemical contamination;

(iv)Pesticides;
(v) Drug residues;
(vi) Decomposition in scombroid toxin-forming species or in any other species where afood safety hazard has been associated with decomposition;
(vii)Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;
(viii)Unapproved use of direct or indirect food or color additives; and
(ix)Physical hazards;
(2)List the critical control points for each of the identified food safety hazards, including as appropriate:
(i)Critical control points designed to control food safety hazards that could be intro- duced in the processing plant environment; and
(ii)Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;
(3)List the critical limits that must be met at each of the critical control points;
(4)List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
(5)Include any corrective action plans that have been developed in accordance with Sec.123.7(b), to be followed in response to deviations from critical limits at critical control points;
(6)List the verification procedures, and frequency thereof, that the processor will use in ac- cordance with Sec. 123.8(a);
(7)Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(d)Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.
(2)The HACCP plan shall be dated and signed:
(i) Upon initial acceptance;
(ii) Upon any modification; and
(iii) Upon verification of the plan in accordance with Sec. 123.8(a)(1).

(e)Products subject to other regulations. For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of Clostridium botulinum toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

(f)Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Sec. 123.11(b) they need not be included in the HACCP plan, and vice versa.

(g)Legal basis. Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

§ Sec. 123.7 Corrective actions.

(a)Whenever a deviation from a critical limit occurs, a processor shall take corrective action eitther by:
(1) Following a corrective action plan that is appropriate for the particular deviation, or
(2) Following the procedures in paragraph (c) of this section.

(b)Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with Sec. 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:
(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and
(2) The cause of the deviation is corrected.

(c)When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:
(1) Segregate and hold the affected product, at least until the requirements of paragraphs(c)(2) and (c)(3) of this section are met;
(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Sec. 123.10;
(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
(4) Take corrective action, when necessary, to correct the cause of the deviation;
(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Sec. 123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(d)All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Sec. 123.8(a)(3)(ii) and the recordkeeping requirements of Sec. 123.9.

§ Sec. 123.8 Verification.

(a)Overall verification. Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1)Reassessment of the HACCP plan. A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10. The HACCP plan shall be modified immedi- ately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Sec. 123.6(c).

(2)Ongoing verification activities. Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii)The calibration of process-monitoring instruments; and,

(iii)At the option of the processor, the performing of periodic end-product or in-process testing.

(3)Records review. A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii)The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and

(iii)The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a mini- mum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b)Corrective actions. Processors shall immediately follow the procedures in Sec. 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c)Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10.

(d)Recordkeeping. The calibration of process-monitoring instruments, and the performing of any

periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of Sec. 123.9.

§ Sec. 123.9 Records.

(a)General requirements. All records required by this part shall include:
(1) The name and location of the processor or importer;
(2) The date and time of the activity that the record reflects;
(3) The signature or initials of the person performing the operation; and
(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b)Record retention.
(1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.
(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.
(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(c)Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

(d)Public disclosure. (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in Sec. 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in Sec. 20.61 of this chapter.
(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e)Tags. Tags as defined in Sec. 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of Sec. 123.28(c).

(f)Records maintained on computers. The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

Sec. 123.10 Training.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a)Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 123.6(b);

(b)Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and

(c)Performing the record review required by Sec. 123.8(a)(3); The trained individual need not be an employee of the processor.

§ Sec. 123.11 Sanitation control procedures.

(a)Sanitation SOP. 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. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b)Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1)Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(2)Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3)Prevention of cross-contamination from insanitary objects to food, food packaging mate- rial, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(4)Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5)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;

(6)Proper labeling, storage, and use of toxic compounds;

(7)Control of employee health conditions that could result in the microbiological contamina- tion of food, food packaging materials, and food contact surfaces; and

(8)Exclusion of pests from the food plant.

The processor shall correct in a timely manner, those conditions and practices that are not met.

(c)Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of Sec. 123.9.

(d)Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by Sec. 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

§ Sec. 123.12 Special requirements for imported products.

This section sets forth specific requirements for imported fish and fishery products.

(a)Importer verification. Every importer of fish or fishery products shall either:

(1)Obtain the fish or fishery product from a country that has an active memorandum of under- standing (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or
(2)Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:
(i)Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,
(ii)Affirmative steps that may include any of the following:
(A)Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;
(B)Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the im-ported fish or fishery product is or was processed in accordance with the require-ments of this part;
(C)Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;
(D)Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;
(E)Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,
(F)Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b)Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c)Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of Sec. 123.9.

(d)Determination of compliance. There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B—Smoked and Smoke-flavored Fishery Products

§Sec. 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

§Sec. 123.16 Process controls.

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by Clostridium botulinum for at least as long as the shelf life of the product under normal and moderate abuse conditions.

Subpart C—Raw Molluscan Shellfish

§Sec. 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

§Sec. 123.28 Source controls.

(a)In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b)Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.

(c)To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in Sec. 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in Sec. 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:
(1) The date of harvest;
(2) The location of harvest by State and site;
(3) The quantity and type of shellfish;
(4) The date of receipt by the processor; and
(5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

(d)To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with Sec. 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document: (1) The date of receipt;
(2) The quantity and type of shellfish; and
(3) The name and certification number of the packer or repacker of the product.

Part 1240—Control of Communicable Diseases

2. The authority citation for 21 CFR part 1240 continues to read as follows:
AUTHORITY: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).
3. Section 1240.3 is amended by revising paragraph (r), and by adding new paragraphs (s), (t), and (u) to read as follows:

§Sec. 1240.3 General definitions.

(r) Molluscan shellfish. Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

(s) Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(t) Shellfish control authority means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(u)Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

4. Section 1240.60 is amended by revising the section heading, by redesignating the existing text as paragraph (a) and adding the word "molluscan" before the word "shellfish" the two times that it appears, and by adding new paragraphs (b), (c), and (d) to read as follows:

§ Sec. 1240.60 Molluscan shellfish.

(b)All shellstock shall bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

(c)All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.

(d)Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

Appendix B
Good Manufacturing Practices

Appendix VI: Current Good Manufacturing Practices (21CFR110)

Authority: Secs. 402, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

Source: 51 FR 24475, June 19, 1986, unless otherwise noted.

Subpart A — General Provisions

§110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a)Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below.

(b)Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c)Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d)Blanching except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e)Critical control point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) Food means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g)Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

(h)Lot means the food produced during a period of time indicated by a specific code.

(i) Microorganisms means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those mi-

croorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.

(j)Pest refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k)Plant means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l)Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m)Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n)Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

(o)Sanitize means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p)"Shall" is used to state mandatory requirements.

(q)"Should" is used to state recommended or advisory procedures or identify recommended equipment.

(r)Water activity (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§110.5 Current good manufacturing practice.

(a)The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and

definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b)Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a)Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b)Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:
(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
(2) Maintaining adequate personal cleanliness.
(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c)Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d)Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§110.19 Exclusions.

(a)The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b)FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B — Buildings and Facilities

§110.20 Plant and grounds.

(a)Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:
(1)Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
(2)Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
(3)Adequately draining areas that may contribute contamination to food by seepage, footborne filth, or providing a breeding place for pests.
(4)Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b)Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1)Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2)Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3)Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii)Controlling areas over and around the vessels to eliminate harborages for pests.

(iii)Checking on a regular basis for pests and pest infestation.

(iv)Skimming the fermentation vessels, as necessary.

(4)Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5)Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6)Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7)Provide, where necessary, adequate screening or other protection against pests.

§110.35 Sanitary operations.

(a)General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b)Substances used in cleaning and sanitizing; storage of toxic materials.

(1)Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii)Those necessary for use in laboratory testing procedures;

(iii)Those necessary for plant and equipment maintenance and operation; and

(iv)Those necessary for use in the plant's operations.

(2)Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c)Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d)Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of micro-organisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e)Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a)Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b)Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:
(1) Carry sufficient quantities of water to required locations throughout the plant.
(2) Properly convey sewage and liquid disposable waste from the plant.
(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c)Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d)Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:
(1) Maintaining the facilities in a sanitary condition.
(2) Keeping the facilities in good repair at all times.
(3) Providing self-closing doors.
(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e)Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
(2) Effective hand-cleaning and sanitizing preparations.
(3) Sanitary towel service or suitable drying devices.
(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f)Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C — Equipment

§110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with

§110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a)Raw materials and other ingredients.

(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6)Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7)Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b)Manufacturing operations.

(1)Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2)All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of micro-organisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3)Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i)Maintaining refrigerated foods at 45 F (7.2 C) or below as appropriate for the particular food involved.

(ii)Maintaining frozen foods in a frozen state.

(iii)Maintaining hot foods at 140 F (60 C) or above.

(iv)Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4)Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling,

and distribution to prevent food from being adulterated within the meaning of the act.
(5)Work-in-process shall be handled in a manner that protects against contamination.
(6)Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.
(7)Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufac-turing or storage in a manner that protects against contamination.
(8)Effective measures shall be taken to protect against the inclusion of metal or other extraneeous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.
(9)Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.
(10)Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.
(11)Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.
(12)Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:
(i)Using ingredients free of contamination.
(ii)Employing adequate heat processes where applicable.
(iii)Using adequate time and temperature controls.
(iv)Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
(v)Cooling to an adequate temperature during manufacturing.
(vi)Disposing of batters at appropriate intervals to protect against the growth of microorganisms.
(13)Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:
(i)Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
(ii)Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii)Using materials for food containers and food-packaging materials that are safe and suitable, as defined in f130.3(d) of this chapter.
(iv)Providing physical protection from contamination, particularly airborne contamination.
(v)Using sanitary handling procedures.
(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:
(i)Monitoring the a_w of food.
(ii)Controlling the soluble solids-water ratio in finished food.
(iii)Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level.
(15)Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:
(i)Monitoring the pH of raw materials, food in process, and finished food.
(ii)Controlling the amount of acid or acidified food added to low-acid food.
(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.
(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

§110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F — [Reserved]

Subpart G — Defect Action Levels

§110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a)Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b)Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c)Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d)The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e)A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

Appendix C
Blank Forms

DAILY SANITATION CONTROL RECORD

Report Date:_____ Firm Name:_____

Line 1: Raw Seafood (not ready-to-eat) Firm Address:_____
Line 2: Ready-to-eat

Sanitation Area and Goal	Pre-Op Time:	Start Time:	4 Hour Time:	8 Hour Time:	Post-Op Time:	Comments and Corrections
1) Safety of Water (See Monthly Sanitation Control Record) ◆ Back Siphonage-Hose (S/U)						
2) Condition and Cleanliness of Food Contact Surfaces (See Monthly Sanitation Control Record) ◆ Equipment cleaned and sanitized Line 1: (S/U)						
Line 2: (S/U)						
◆ Sanitizer Strength Sanitizer Type:_____ Strength:_____ ppm						
Line 1: (ppm)						
Line 2: (ppm)						
◆ Gloves and aprons clean and in good repair Line 1: (S/U)						
Line 2: (S/U)						
3) Prevention of Cross-Contamination (See Monthly Sanitation Control Record) ◆ Hands, gloves, equipment, and utensils washed/sanitized after contact with unsanitary objects (S/U)						
◆ Employees working on raw products, wash and sanitize hands/ gloves/outerwear before working with cooked products (S/U)						
◆ Unpackaged cooked products separated from raw products (S/U)						

S = Satisfactory / U = Unsatisfactory

Continued (page 2)

Daily Sanitation Control Record (page 2)

Sanitation Area and Goal	Pre-Op Time:	Start Time:	4 Hour Time:	8 Hour Time:	Post-Op Time:	Comments and Corrections
4) Maintenance of Hand-washing, Hand-sanitizing, and Toilet Facilities ◆ Hand-washing and hand-sanitizing stations adequate • Hand-washing station Line 1: (S/U) Line 2: (S/U) • Hand-sanitizing station Sanitizer Type_____ Strength:_____ ppm Line 2: (ppm) ◆ Toilets clean, properly functioning, and adequately supplied (S/U)	☐ ☐ ☐ ☐		☐	☐		
5) Protection from Adulterants and 6) Labeling, Storage, and Use of Toxic Compounds ◆ Product protected from contamination (S/U) ◆ Cleaning compounds, lubricants, and pesticides labeled and stored properly (S/U)	☐	☐	☐	☐		
7) Employee Health Conditions ◆ Employees do not show signs of medical problems (S/U)	☐					
8) Exclusion of Pests ◆ Pests excluded from processing area (S/U)	☐					

S = Satisfactory / U = Unsatisfactory

Signature or initials _____ Date_____

Monthly Sanitation Control Record

Report Date:_____ Firm Name:_____

Firm Address:_____

Sanitation Area	Decision	Comments/ Corrections
1) Safety of Water ◆ Safe and sanitary source (S/U) (annual) ◆ No cross-connections in hard plumbing (S/U)	☐ ☐	
2) Condition and Cleanliness of Food Contact Surfaces ◆ Processing equipment and utensils in suitable condition (S/U)	☐	
3) Prevention of Cross-contamination ◆ Physical conditions of plant and layout equipment (S/U)	☐	

S = Satisfactory / U = Unsatisfactory

Additional Comments:

Signature or initials _____