

Food Safety in **Shrimp** Processing

A HANDBOOK
FOR SHRIMP
PROCESSORS,
IMPORTERS,
EXPORTERS AND
RETAILERS

L. KANDURI AND
R. A. ECKHARDT



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**A Handbook for Shrimp Processors,
Importers, Exporters and Retailers**

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Contents

<i>Foreword</i>	ix
<i>Preface</i>	xiii
<i>Acknowledgments</i>	xvii
1 Introduction to Hazard Analysis Critical Control Points (HACCP)	1
1.1 Introduction	1
1.2 What is HACCP?	1
1.3 How is the HACCP-based approach different from the traditional food safety systems?	2
1.4 Scope of HACCP	2
1.5 Various federal regulatory agencies and their role in regulating seafood in the United States	3
1.5.1 United States Department of Health and Human Services (DHHS)/Food and Drug Administration (FDA)	3
1.5.2 United States Department of Commerce (USDC)/National Oceanic and Atmospheric Administration (NOAA)/National Marine Fisheries Service (NMFS)	4
1.5.3 Other federal agencies	4
1.6 HACCP and the US seafood industry	5
1.7 Implementation of HACCP in the United States	5
1.8 Rationale for the FDA's adoption of a HACCP-based approach to seafood inspection	6
1.9 What are the practical implications for American seafood processors and processors from other countries?	6
1.9.1 Summary of the US HACCP regulations	6
1.9.2 What are the benefits attributed to the HACCP regulations?	8
1.9.3 HACCP and the Export Health Certificate	8
1.10 Who is excluded?	9
1.11 HACCP v. ISO standards	9
1.12 Relevance of HACCP to shrimp culture and processing	11
1.13 Current world status of HACCP in shrimp culture and processing	12
2 Implementing Sanitation and Related Programs as a Prerequisite to HACCP	15
2.1 Introduction	15
2.2 Sanitation, the most important prerequisite to HACCP, and what it actually means to a processor	15
2.3 What are the benefits of sanitation?	16

2.4	Regulatory requirements	16
2.5	How to comply with sanitation requirements under the HACCP regulations	17
2.5.1	Premises	17
2.5.2	Transportation and storage (raw materials, ingredients and packaging materials)	20
2.5.3	Equipment (design, installation and maintenance)	21
2.5.4	Personnel (training in manufacturing controls and hygienic practices)	21
2.5.5	Sanitation and pest control	21
2.6	How to develop sanitation SSOPs to comply with the proposed HACCP-based regulations	21
2.6.1	Cleaning schedule	22
2.6.2	Wash facilities	24
2.6.3	Personnel	24
2.6.4	Restrooms	24
2.6.5	Water supply	24
2.6.6	Waste disposal	24
2.6.7	Chemicals	25
2.6.8	Pest control	25
2.6.9	Records	25
3	Developing a HACCP Plan	26
3.1	What must be in a HACCP plan and how to implement a HACCP-based system	26
3.1.1	Assembling a HACCP team and assigning responsibilities	26
3.1.2	Developing an organizational chart and narrative	27
3.1.3	Describing the intended use of the end product and its distribution	27
3.1.4	Identifying product ingredients and incoming materials	28
3.1.5	Developing an operational flowchart depicting the control points of a process in question	28
3.1.6	Developing a plant schematic	28
3.2	Developing a Hazard Analysis (HA) worksheet following the seven principles of HACCP	29
3.2.1	First principle of HACCP – identify potential hazards and appropriate preventive measures	29
3.2.2	Second principle of HACCP – determine critical control points (CCPs)	32
3.2.3	Third principle of HACCP – establish critical limits (CLs)	35
3.2.4	Fourth principle of HACCP – establish monitoring procedures (MPs)	35
3.2.5	Fifth principle of HACCP – set corrective action (CA) protocols to deviations	37
3.2.6	Sixth principle of HACCP – establish verification procedures	37
3.2.7	Seventh principle of HACCP – establish procedures for record keeping	39

4	HACCP in Shrimp Processing	40
4.1	Introduction to HACCP in shrimp processing	40
4.1.1	Background	40
4.1.2	Major cold-water shrimp species	40
4.1.3	Tropical shrimp species	41
4.1.4	Freshwater shrimp	41
4.1.5	Product/market forms and definitions	42
4.2	Processing (raw)	42
4.2.1	Grading (size and counts)	44
4.2.2	Beheading	45
4.2.3	Peeling and deveining	45
4.3	Processing (cooked)	47
4.4	Dried shrimp	47
4.5	Canning	49
4.6	Breeding	49
4.7	Freezing	51
4.7.1	Glazing	52
4.8	Cold storage	53
4.9	Ice production and storage	53
4.10	HACCP in shrimp processing	53
4.10.1	General guidelines in developing a HACCP plan	53
5	General Concepts of Sampling and Monitoring	65
5.1	Introduction	65
5.2	Basics of sampling	66
5.2.1	Major disadvantages of sampling	66
5.2.2	When is sampling used?	66
5.2.3	When is sampling most effective?	66
5.3	Definitions of basic sampling terms	66
5.4	Types of sampling plans	67
5.4.1	Attribute plans	68
5.5	Ten percent rule	70
5.6	Resampling	70
5.7	Statistical process/quality control	71
6	Sampling Procedures and Monitoring for Organoleptic, Physical and Chemical Quality	72
6.1	Sampling schedule	72
6.2	Organoleptic analysis	73
6.2.1	Physical requirements of organoleptic examination	73
6.2.2	Other considerations	73
6.2.3	Procedure	73
6.2.4	Regulatory action guidance	75
6.3	Physical testing	76
6.3.1	Net weight	76
6.3.2	Determination of the physical parameters	77
6.3.3	Determination of filth in shrimp	79

6.3.4	Flesh content of frozen breaded shrimp	80
6.3.5	Standard cooking procedure	80
6.4	Chemical testing	81
6.4.1	Phosphorus (phosphates)	82
6.4.2	Sulfites	83
6.4.3	Indole test for decomposition	84
7	Monitoring for Microbiological Quality	87
7.1	Introduction	87
7.1.1	What are microorganisms?	87
7.2	Features that are unique to microorganisms	87
7.3	Factors that influence the growth of microorganisms	88
7.3.1	External factors	88
7.3.2	Internal factors of the substrate	88
7.3.3	Interaction between growth factors	88
7.4	Microorganisms and their effect on humans	88
7.4.1	Pathogenic	89
7.4.2	Spoilage causing	89
7.5	Classification of bacteria	89
7.5.1	Stain	89
7.5.2	Based on their oxygen requirements	90
7.6	Microbiological testing procedures	90
7.6.1	Standard plate count (SPC)/total viable count (TVC)/ total plate count (TPC)/aerobic plate count (APC)	90
7.6.2	Total coliform and <i>E. coli</i> counts	92
7.6.3	<i>Salmonella</i> spp.	93
7.6.4	<i>Listeria monocytogenes</i>	98
7.6.5	<i>Staphylococcus aureus</i>	103
8	The Future of HACCP in Controlling Seafood Safety	105
	References	107
	Appendices	111
1	Forms for Evaluating Prerequisite Programs	113
2	Example of a Daily Sanitation Report	127
3	An Illustrated Example of a HACCP Plan – Processing Cooked Shrimp	129
4	Example of Detailed Product Specifications for Fresh and Frozen Green Headless and PUD Shrimp	142
5	Raw Material Evaluation Worksheet	145
6	HACCP Regulations	146
7	Abbreviations Used in This Book	159
8	Recommendations for Factory Vessels	161
9	Celsius–Fahrenheit Temperature Conversions	165
10	Conversion Factors	166
	Index	167

Foreword

It is encouraging to a president to see writing and research with very practical applications in the real world. Institutions of higher education receive criticism about being out of touch. In this publication, one can see the direct benefits to be derived by people in the field of endeavor. The authors are demonstrating what is right about the balance between teaching, research and service. There are elements of all three in this project.

These professional colleagues are to be commended for balancing teaching responsibilities while working on a project of this magnitude. Given the popularity of shrimp in the United States, their work can also help safeguard the people of this country through the supply of safe food.

Byron N. McClenney
President
Kingsborough Community College

Dedicated to my late parents, my wife and children for
their unstinting patience and understanding
L.K.

Preface

Shrimp and prawns belong to the phylum Arthropoda, the largest phylum in the animal kingdom, in the class Crustacea, order Decapoda. In the North American context, the term *prawn* most commonly describes a large size shrimp, but is also used in reference to the freshwater variety. Physically they look very similar but there is one major way to tell them apart. In shrimp, the side plate of the second segment of the abdomen overlaps the segments in front and behind; prawns have all the abdominal side plates overlapping tile-like from the front. A more fundamental difference is that female prawns do not brood eggs, but shed them into the water currents where they develop independently.

Of more than 30 families and hundreds of species of shrimp, 344 species are currently recognized as potentially important commercial food sources. Most are marine in origin although some live in estuaries, rivers and lakes. Most shrimp are scavengers, living close to the bottom or swimming in mid-water along with plankton, others are active predators.

About 60% of the world's supply is still wild-caught and diverse, living in a wide range of habitats. These habitats have a bearing on the types of microflora, toxins, parasites, chemicals and other potential hazards that they may be exposed to and that can subsequently affect human food safety.

There has been a general decline in marine resources due to limitations in wild catch and conservation measures. The increased activity of animal rights groups and environmental awareness in people has led to a gradual shift of seafood from capture to culture. However, diseases and environmental factors coupled with prevailing El Niño and La Niña effects and drought have led to a recent substantial fall in production from aquaculture. Shrimp and prawn from aquaculture amounted to about 41% of the total production in 1998 (FAO, 2000).

Tropical shrimp is presently farmed in over 50 countries. The Western hemisphere produces approximately 20% and the Eastern hemisphere about 80% of the world's farm-raised shrimp. Most of the farm-raised shrimp that enters the global market comes from developing countries ranging from Asia, the Far East (e.g. Thailand, China and India) to South and Central America (e.g. Mexico and Ecuador).

Shrimp and prawn are the most important high value seafood entering world trade channels, accounting for over 20% of total seafood trade value. They have excellent potential as an export item and hard currency earner for many of the developing countries. The advent of large-scale shrimp culture led to a remarkable rise in production by the mid-1990s. According to its monetary value, the giant tiger prawn (*Penaeus monodon*) ranks first among all aquacultured species. A great quantity of shrimp (wild-caught and farm raised) is imported into the developed countries from every region of the world.

Amongst foods, seafood is the most perishable of all. It is harvested and processed in a wide array of circumstances, often in remote, under-equipped and unsanitary conditions. Therefore shrimp, whether wild-caught or cultured, is subjected to a wide range of safety hazards. This has prompted the importing countries to tighten quality requirements, revising food sanitation laws and hygienic standards, which often results in import restrictions and embargoes. The impact of globalization and liberalization on international trade is driving us towards the establishment of a harmonized system of food inspection. Exporting countries recognize the need for such a harmonization and are forced to incorporate changes in their inspection, quality control and environmental regulations. The international scientific community has agreed on the benefits of applying the principles of Hazard Analysis Critical Control Points (HACCP), a system that is based on establishing preventive controls for attaining food safety. When HACCP is applied by the industry, health hazards are prevented or minimized. More importantly, HACCP is not a system operated by the government. The role of government regulatory agencies such as the United States Food and Drug Administration (USFDA) is limited to verification. USFDA, through its inspections, verifies that the HACCP systems established and operated by the industry are adequate and working, and implements corrective action(s) when they are not.

While the system of producing food under HACCP principles was being internationally evaluated and endorsed, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) adopted it as the basis of their seafood, meat and poultry inspection policy, respectively.

A 'HACCP-based approach' to produce safe food has already been accepted as a standard system by the European Union (EU), Canada, Australia, New Zealand and Japan for their own industry as well as for those who export to these countries. The Organization for Economic Cooperation and Development (OECD) member countries – Belgium, Canada, Denmark, UK, France, Germany, Greece, Iceland, Japan, Korea, Mexico, Netherlands, New Zealand, Norway, Spain, Sweden, and the United States – have already accepted and started implementing HACCP-based inspection of seafood. Non-OECD countries such as Estonia, Lithuania and Russia are currently evaluating the implementation of HACCP. In January 1998 a workshop on 'Seafood Safety' was organized by the OECD and held at the OECD headquarters in Paris. The main objective was to offer OECD countries a special forum for discussion on fish inspection procedures, aiming to achieve the desirable 'equivalence'. HACCP can contribute to the process of making determinations about equivalence between different seafood inspection systems.

In Australia, all fishing boats will have an internationally recognized safe food assurance system installed by 2002. This will be accredited and regularly audited by a government-approved third party. The HACCP system is presently the minimum system allowed. HACCP is part of the quality safe foods 2000 (SQF 2000) program instituted in Australia, and was developed in 1997. It has been installed on about 300 farms and 200 food processing plants and is acknowledged to be the most suitable system for fishing boats. Major Australian supermarkets are beginning to insist that primary producers have a HACCP-approved system in place.

Similarly, the UK is gearing up to help implement HACCP-related programs in the countries of Eastern Europe and the Commonwealth of Independent States.

Through organizing symposia, UK universities, with the active support of The Food and Agriculture Organization of the United Nations (FAO) are currently addressing a number of important topics related to business and trade in privately owned fisheries enterprises, including quality assurance and hygiene in relation to international trade compliance, and training in total quality management and HACCP.

This book is intended to serve as a comprehensive source of information for producing safe seafood in general and in particular prawn/shrimp products. The relevant government regulations are elaborated in simple language for the benefit of commercial seafood processors, exporters, importers, food technologists, food chemists and food inspectors. This publication:

- Introduces details of the development of appropriate sanitation procedures that provide a firm foundation for the implementation of HACCP in seafood processing operations. It also includes sanitation requirements and recommendations for fishing vessels.
- Explains the HACCP principles and hazard analysis application to various steps in processing.
- Explains in detail the North American (Canadian and US) HACCP regulations that are already in place.
- Includes an explanation of the important differences between HACCP and the International Standards Organization, ISO 9000/14000 series of standards.
- Explains hazard analysis for processing raw, cooked, breaded, dried and frozen shrimp.
- Includes HACCP plan forms with examples of completed forms. The hazard analysis information provided is useful in developing HACCP plans for firms involved in shrimp aquaculture and processing.
- Provides details of sampling and its application in the shrimp processing industry for the benefit of processors. Sampling and monitoring are the most crucial components of a HACCP-based inspection system.
- Gives examples of some of the latest techniques to monitor physical, chemical, organoleptic and microbiological quality of shrimp. Recent developments in rapid microbial detection (RMD) with examples of some procedures have been included.
- Provides details of product specifications and raw material evaluation (important requirements for every seafood importer when a product is received from those countries without an active memorandum of understanding) for shrimp, for the use of processors and importers.
- Provides a list of the most recent subject-specific Internet sites.

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1 Introduction to Hazard Analysis Critical Control Points (HACCP)

1.1 INTRODUCTION

This chapter explains the nature and scope of the Hazard Analysis Critical Control Points (HACCP) system and its relevance in the United States, along with implications and development in other parts of the world. HACCP v. the ISO 9000/14000 series of standards are also explained.

The HACCP system has been recognized throughout the developed world as a major advance in safety assurance systems. A HACCP-based system of inspection is recommended by the United States National Academy of Sciences (NAS) and was mandated for implementation by the Food and Drug Administration (CFR, 1995) and United States Department of Agriculture (USDA, 1995). It provides food producers and processors with a standard system for carrying out and managing their activities in such a way that the end product is safe for human consumption.

The FDA began to explore the feasibility of mandating HACCP controls for food safety and proposed a HACCP-based system for seafood in January 1994. The final regulations were issued in December 1995 (CFR, 1995). The provisions under these regulations took effect on 18 December 1997, two years after their original date of publication in the Federal Register. This publication deals with the principles and application of HACCP to seafood in general, and processing of shrimps in particular. Although the information provided is more relevant to the United States, the principles are applicable to the seafood industry of any other country interested in implementing HACCP-based inspection systems.

1.2 WHAT IS HACCP?

The HACCP-based inspection system was first conceived by The Pillsbury Company and was used to develop safe food for astronauts in collaboration with NASA and the US Army Laboratories at Natick, MA, USA. The original approach to HACCP was based on Failure, Mode and Effect Analysis (FMEA) as applied to engineering systems, where each step of an operation is carefully examined for potential mistakes that can occur, along with possible causes and their likely effects on a finished product. Effective control mechanisms are then put in place to ensure that such potential failures are prevented.

HACCP is also a preventive system of quality control and was developed to minimize consumer risk of illness and injury from foods. Its goal is to prevent the hazards at the earliest possible stage of food processing. It enables food processors to identify, prioritize and minimize various likely hazards. It enables consideration of all the factors that contribute to most outbreaks and of risk-assessment techniques.

The basic premise is that if each step of the process is carried out correctly, the end product will be safe food.

However, to effectively implement a HACCP-based system a sound sanitation program must be in place. In other words, effective sanitation operation procedures become the foundation for application of HACCP to food processing.

HACCP places the onus on processors who must demonstrate to themselves and to the regulatory agencies that the food produced in their establishment is safe, and that production is adequately controlled as a matter of design.

HACCP treats the production of food as a total continuous 'system' assuring food safety from harvest to consumption. Potential benefits include improvement in quality and lowered costs of manufacturing. The system is broken down into components and each component is evaluated. The application of HACCP allows the management to control any area or point in the food system that could contribute to a hazardous situation. Examples of hazards may be any of the following: contaminants, pathogenic microorganisms, physical objects and chemicals.

1.3 HOW IS THE HACCP-BASED APPROACH DIFFERENT FROM THE TRADITIONAL FOOD SAFETY SYSTEMS?

The traditional method for assessing food safety provides only a 'snapshot' of conditions at the time of inspection, whether it is conducted in-house or by a third party such as a regulatory agency. However, assumptions must be made about the conditions before and after that inspection on the basis of the 'snapshot' which may or may not be close to reality.

HACCP takes a proactive approach to food safety. The understanding and application of HACCP principles means that the primary responsibility for demonstrating that hazards specific to the foods they produce are being prevented rests with the industry. In other words, HACCP enables industry to perform self-inspection combined with government monitoring to assure food safety.

NAS has recommended that HACCP be implemented by the food industry and that it be incorporated into federal food inspection programs in the US. The unique nature of the commercial seafood industry made it the first to use HACCP on an industry-wide basis.

1.4 SCOPE OF HACCP

Historically, the principal focus of HACCP has been food safety and the FDA regulations (see Appendix 6 for details) in the United States mandating HACCP-based inspection system are limited to food safety.

HACCP concepts can be applied in development of a comprehensive product control system where all phases of safety, as well as other nonsafety related hazards such as wholesomeness (quality) and economic fraud can be addressed at the same time. One example of this is the comprehensive voluntary HACCP system offered to individual companies by the United States National Marine Fisheries Service (NMFS) by charging them for their service.

1.5 VARIOUS FEDERAL REGULATORY AGENCIES AND THEIR ROLE IN REGULATING SEAFOOD IN THE UNITED STATES

1.5.1 United States Department of Health and Human Services (DHHS)/Food and Drug Administration (FDA)

FDA/DHHS is primarily responsible for the regulation of all aspects of consumer protection relative to foods and drugs including fish and seafood, whether domestically produced or imported. The authority is granted by the federal Food, Drug, and Cosmetics Safety Act (FDA, 1938), the Fair Packaging and Labeling Act (FDA, 1966), and The Nutrition Labeling and Education Act (CFR, 1997).

Some of the important aspects of the FDA's role in assuring food safety are:

- (1) It has jurisdiction over food in interstate commerce.
- (2) It has authority over domestic and imported food, which includes seafood.
- (3) It enforces good manufacturing practices/regulations.
- (4) It oversees the National Shellfish Sanitation Program (NSSP).
- (5) It monitors and enforces proper food labeling which includes proper weights and seafood species nomenclature, etc.
- (6) It enforces nutritional labeling, health claims and use of food additives.
- (7) It works with various state government agencies to implement/enforce regulations.
- (8) It operates a few focused inspection programs for seafood, the most important being the Low Acid Canned Food (LACF), and Salmon Control Program for canned salmon. These programs rely more on federal presence (inspection) at the firm during production.
- (9) The FDA Office of Seafood opened in March 1991 is specifically dedicated to oversee seafood programs, regulations and issues.
- (10) The FDA's Center for Veterinary Medicine (CVM) is responsible for approving drugs for use in aquaculture and developing and approving methodologies for the detection of drug residues in aquaculture species.

The FDA conducts sanitary inspections of domestic seafood processing operations and evaluates fish handling procedures within each facility. The facility may be a processor, shipper, packer/repacker, labeler/relabeler, warehouse or importer of seafood. Inspectors analyze and test the products produced or stored in these plants for filth, decomposition and contaminants. The FDA has the authority to seize and destroy any unacceptable product, and to impose criminal penalties for improper care, handling or sanitation.

The FDA regulates imported seafood in different ways. First, products are examined and sampled at the wharf and analyzed in the laboratory; products with a history of problems are sometimes detained and will not be accepted unless accompanied by an acceptable certificate of analysis. The FDA also negotiates a Memorandum of Understanding (MOU) with individual foreign governments to improve sanitation at the point of origin.

1.5.2 United States Department of Commerce (USDC)/ National Oceanic and Atmospheric Administration (NOAA)/National Marine Fisheries Service (NMFS)

The NMFS has various roles in seafood safety related aspects:

- (1) It offers a voluntary seafood inspection program and a voluntary HACCP-based inspection program. Such inspections are based on a fee-for-service paid by the participating seafood firm using a predetermined price schedule.
Three optional inspections are offered by the NMFS:
 - (a) Contract inspection: the most comprehensive service evaluating all aspects of seafood preparation, processing and packaging. Seafood processors and packers are primary users of this service.
 - (b) Lot inspection: most often used by brokers or buyers in the distribution chain. The inspection only evaluates the existing product quality and packaging.
 - (c) Consultation services: used to address a specified concern such as plant sanitation, new product quality, overall quality control program, etc.
Such firms are allowed to advertise their product with markings such as PUF (Packed Under Federal Inspection) or SIF (Sanitarily Inspected Fish Establishments), depending on the type of inspection done.
Some private companies, including commercial seafood companies, are currently using NMFS's voluntary HACCP-based inspection. These firms are required to submit comprehensive HACCP plans (safety and nonsafety hazards) which are then accepted by NMFS. NMFS conducts audits of the participating companies with the help of the HACCP plan. The goal of NMFS is to convert their entire voluntary program to HACCP.
- (2) When the US government first declared the 200-mile Exclusive Economic Zone (EEZ) limit, it created several regional fisheries management councils. On the east coast, management is divided among the New England, Mid-Atlantic and Gulf councils. The North Pacific Council is responsible for the entire west coast, including Alaska and the western continental United States. These councils were authorized by the government under the Magnuson Fisheries Conservation and Management Act to manage the resources within each of their regions. NMFS coordinates fisheries management policies and regulations with the regional fisheries management councils.
- (3) It collects and publishes fishing industry statistics.
- (4) It conducts some marine environmental monitoring.
- (5) It provides industry support services.
- (6) It monitors/enforces Marine Mammal and Protected Species Regulations.

1.5.3 Other federal agencies

- (1) The United States Department of Agriculture (USDA) oversees aquaculture marketing and development programs. The National Aquaculture Act (USDA, 1980) designated USDA as the primary federal agency in promoting aquaculture. It offers specific programs to improve marketing, such as the Federal-State

Marketing Program. The USDA's Animal and Plant Health Inspection Service provides diagnostic assistance for the identification and treatment of fish diseases. However, the FDA is still the primary food safety regulatory authority, and it maintains open cooperation with USDA and various states on all pertinent aquaculture issues.

- (2) The Environmental Protection Agency (EPA) is involved in regulating environmental contaminants based on authority provided by the federal Clean Water Act. It recommends and assists the FDA in setting regulatory guidelines for pesticides, heavy metals, petrochemicals and other potential aquatic food contaminants. The federal EPA is also responsible, in part, for maintaining the water quality associated with the production of domestic seafood.
- (3) The Federal Trade Commission (FTC) has primary jurisdiction over advertising of foods under an MOU with FDA. The FTC Act prohibits 'unfair or deceptive acts or practices in or affecting commerce'.
- (4) The US Customs Service is the initial regulatory authority, which controls the entry of seafood imports. They have an established MOU with the FDA such that all food imports are subject to FDA inspection. In reviewing entry notices and other documents provided by US Customs, the FDA can determine whether to release or hold the product for sampling/inspection. If the product is detained, the importer may be permitted to try to bring an illegal importation into compliance with FDA regulations before the US Customs grants final approval for admission. However, the final regulatory scrutiny for quality and safety rests with the FDA.

It also enforces country-of-origin labeling requirements under the Tariff Act (USCS, 1930). Seafood importers must ensure that packaging labels comply with present regulatory standards. The general rule is that the marking of the country of origin label on a seafood package must be 'legible, indelible, and permanent', and written in the English language, unless the Commissioner of Customs specifically authorizes another marking.

1.6 HACCP AND THE US SEAFOOD INDUSTRY

The FDA first announced the 'Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products' in the Federal Register (21 CFR Parts 123 and 1240, 28 January 1994). After allowing a 90-day comment period and reviewing the responses received, the FDA issued the final rule with some revisions. It was published in the Federal Register under 21 CFR, Parts 123 and 1240: 'Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, Final Rule' on 18 December 1995, CFR (1995).

1.7 IMPLEMENTATION OF HACCP IN THE UNITED STATES

The industry in the US was given a two-year implementation period which ended on 18 December 1997. During this time, the industry was to obtain training, write HACCP plans, install the HACCP system, engage in sanitary monitoring, etc. Full mandatory implementation must have taken place by the end of this period.

Between 18 December 1997 and 15 August 1998 the FDA conducted over 2000 inspections of domestic seafood processors, and issued several hundred

untitled letters to seafood processors regarding ways to improve implementation of their HACCP programs. The follow-up inspections by the FDA and state authorities of about 4100 US seafood processors indicated that 29% of the firms were in full compliance to the regulations. Only 4% of the firms warranted regulatory actions because of problems raising significant public health concerns. These inspections recommended substantial improvements to achieve the science-based level of safety assurance that HACCP is intended to provide.

In this context, the FDA has issued two import alerts to provide guidance to its offices on how to respond to lack of verification as required for imported seafood under its Seafood HACCP Regulation.

Import Alert 16–119

Detention without physical examination where the importer has failed to provide verification of compliance. This authority to detain will apply to specific import/processor/product combinations, as listed in Attachment A.

Import Alert 16–120

Detention without physical examination when the foreign processor failed to provide adequate HACCP documentation to US importers for verification as per 2 CFR 123.12(d). An attachment to this import alert contains a list of product(s) to which the guidance applies.

1.8 RATIONALE FOR THE FDA'S ADOPTION OF A HACCP-BASED APPROACH TO SEAFOOD INSPECTION

The official statement of Vice President Al Gore on FDA's Food Safety Initiative explains eloquently the rationale for HACCP:

...The HACCP-based system captures what reinventing government is all about – a fundamental change in the way government does its job. In this case, replacing a one-size-fits-all regulation with a tailored system of preventive controls specific to each product and process that will improve food safety for consumers and respond more efficiently to industry needs.

1.9 WHAT ARE THE PRACTICAL IMPLICATIONS FOR AMERICAN SEAFOOD PROCESSORS AND PROCESSORS FROM OTHER COUNTRIES?

Many countries now accept the HACCP-based system and insist that it is implemented in the production and processing of seafood before they are processed imported or exported. One such example is the US HACCP regulations. US regulations have a major impact on world seafood producers because the US is one of the largest importers of seafood in the world.

1.9.1 Summary of the US HACCP regulations

The HACCP regulations require the system to be built on a firm foundation of producing any/all types food under sanitary conditions. This aspect of the law is

broad based and is already covered under the existing stipulations of 'Current Good Manufacturing Practices (CGMPs): Title 21, Part 110 of the Code of Federal Regulations (CFR, 1981) – Manufacturing, Processing, Packing or Holding Human Food'. Therefore, compliance with the CGMPs and Standard Sanitary Operating Procedures (SSOPs), appropriate training of the personnel, product recall procedures, preventive maintenance, product coding, etc., are a prerequisite before developing and implementing an HACCP program. Guidelines to assessing and developing these programs are provided in Chapter 2.

The FDA HACCP regulations are specific to seafood and are codified under Title 21, Parts 123 and 1240 of CFR (1994): 'Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, Final Rule'. Each aspect of the regulation is explained in detail in later chapters; the following is a brief summary of the HACCP regulations.

HACCP requires that all commercial seafood in interstate commerce be processed under HACCP controls. This includes seafood that has been domestically produced and seafood that is imported. Foreign processors that export to the US must operate under HACCP. Every processor must demonstrate that they have identified all likely safety hazards and are taking measures to prevent them, as a matter of design (for details on developing a HACCP plan, see Chapter 3). In other words:

- (1) Every processor must conduct a hazard analysis to determine whether their product has a potential food safety hazard that they must control. If it is determined that there is no potential hazard, then the processor is not required to have a HACCP plan until such time as a significant change is made to the process. At that time analysis must be done to reassess the hazards. If a hazard is identified, the firm must have and implement a written HACCP plan specific to each plant location and each kind of product processed.
- (2) Failure to establish and implement a plan means the processor or importer's products shall be considered to be adulterated.
- (3) Monitoring must follow proper recording; if deviations occur, appropriate corrective action must be undertaken. Consumer complaints related to critical control points shall also trigger corrective action.
- (4) Records must identify the product, product code, and date of activity. Records must be on line rather than retroactive. They must be reviewed and signed by a trained individual. They must be retained for at least one year after preparation for refrigerated products, and for two years after preparation for frozen or preserved products, and be made available to FDA inspectors.
- (5) Processor is responsible for performing sanitation inspections and assuring compliance with Good Manufacturing Practices (GMPs). The regulations specify sanitation procedures and refrigeration levels. Sanitation inspection must be documented.
- (6) The FDA will then evaluate how well their systems are working, as part of its mandatory inspection program.
- (7) Importers must take affirmative steps to verify that their foreign suppliers are operating under HACCP regulations. Importers need not take any verification steps if they are importing from a country that has entered into an agreement

with the United States that establishes the equivalency of the regulatory systems of the two countries.

These regulations encourage, but do not require, that processors and importers adopt the same types of controls for nonsafety hazards that are not associated with human illness and economic adulteration, such as decomposition and filth.

1.9.2 What are the benefits attributed to the HACCP regulations?

Instead of a 'snapshot' provided by current inspections, HACCP implementation would benefit both the regulators and the processor. The HACCP-based approach to food safety is not only more efficient but cost-effective to all, including the consumer, for the following reasons. It will enable:

- (1) An FDA investigator to see how an importer or a processor operates over a period of time.
- (2) Determination of whether problems have occurred, and how they were addressed.
- (3) A processor to spot trends that could lead to problems, and help prevent them from occurring.
- (4) The processor/regulator to review the adequacy of the processor's or importer's preventive controls.
- (5) The identification of inadequate preventive controls that warrant remedial or regulatory action regardless of whether the processor's or importer's product is actually unsafe.

1.9.3 HACCP and the Export Health Certificate

HACCP has been endorsed worldwide including by Codex Alimentarius (a commission of the United Nations), the EU, Canada, Australia, New Zealand and Japan. The EU requires that the competent authority of a third country (in the US, FDA/NMFS) that exports fishery products to the EU provide a list of approved establishments. In addition to firms being listed, the EU requires that all seafood products produced for export to the EU on or after 1 January 1996 must be processed using HACCP principles. Exporters that do not process themselves must provide assurance to the FDA that the fishery products offered for export to the EU are processed at establishments in the US that apply HACCP principles. Such exporters are identified on the US list by an asterisk (*) symbol preceding their name. The asterisk refers the user of the US list to the note on each page of the US list that states '*Before a name indicates: EXPORTER OTHER THAN PROCESSOR'.

Each processor/exporter will be assigned a Central File Number (CFN) for each product and packing type. The EU requires that each exterior container, carton or label of product covered by an EU Export Health Certificate bear the CFN identification number. Only one CFN may appear on each exterior container, carton or label. The CFN on the container, carton or label must match the CFN written in the EU Health Certificate, or the product will be detained or refused entry into the EC countries. Similarly, other seafood exporting countries maintain a list of government-approved processors on their respective websites. Such lists are periodically updated for the benefit of the regulatory agencies and importers.

1.10 WHO IS EXCLUDED?

The proposed regulations do not apply to fishing vessels except processing vessels, retailers, food service establishments and transporters. However, for reasons discussed later in this chapter, the HACCP concept is likely to be extended to all types of food production and processing, including aquaculture.

1.11 HACCP v. ISO STANDARDS

In addition to HACCP, other quality systems gaining worldwide recognition are the International Organization for Standardization (ISO) series of standards for quality management and environmental management. First adopted and issued in 1987, ISO 9000 standards define the principles that should be adhered to within a quality system.

The purpose is to level the playing field for the management of quality for the world's commercial products and services, so that all nations will have a common basis for acceptance of each other's goods in free trade. ISO standards (ISO 1998a, b) are known as generic management system standards. The 'product' could be an actual product or even a service provided to the consumer. 'Management system' means what an organization does to manage its activities. To be efficient and effective an organization can manage its operation by systemizing its practices. This ensures that nothing important is left out and that everyone is clear about who is responsible for doing what, when, how, why and where. Management system standards provide the organization with a model to follow in setting up and operating the management system.

The objectives of the quality system are to achieve and sustain the quality of the product so as to meet the buyer's needs and to provide confidence to management and buyers that the intended quality is achieved. Other benefits include consistency and guidance in establishing quality systems and procedures for independent audits of these systems. The ISO standards are written in mandatory terms so that they can be used as a contract between supplier and buyer.

The standards are designed to protect the supplier as much as the buyer. The use of ISO standards requires a quality manual, standard operating procedures and documentation (record keeping). The standards also require audits of an organization's quality system; both internal and external audits are expected under ISO. Once an organization has established a quality system according to the guidelines in the standard and the appropriate quality assurance model, the firm can then become certified or registered (terms used interchangeably in some countries).

ISO auditing and certification for ISO 9000 and ISO 14000 are carried out independently of ISO by certification bodies under their own responsibility. These third party organizations are referred to in some countries as 'registration bodies' or 'registrars'.

Many US manufacturing firms are becoming ISO certified in the belief that it will provide easier access to the EU market. While US manufacturers are not obliged to follow the standards, the ability to get their products into the EU market will depend upon the member countries' willingness to accept test reports and certificates. Clearly US firms who are not ISO certified will have a more difficult time exporting to EC members than ISO certified firms.

It is ISO policy to review and update each issued ISO standard approximately every five years. The purpose is to ensure that the standards are consistent with the contemporary state of the art and proven implementations of the field of business practice involved. The standard underwent a relatively minor, primarily clarifying, update in 1994, but the 2000 update is a major structural and strategic revision of the 9000 series of standards. It incorporates several concepts that will bring the standard into better alignment with what are widely considered to be 'best practice' strategies for contemporary quality management systems. The Year 2000 revisions of ISO's 9000 series of quality management standards have progressed to the stage of Draft International Standards (DIS) and were published in December 2000 (<http://www.iso.ch>).

Summary of the Year 2000 revisions of ISO 9000 (ISO Bulletin, 1999)

The new standard will consist of three basic parts:

ISO 9000 – Fundamentals and vocabulary

ISO 9001 – Requirements

(The old ISO 9002 and 9003 standards became obsolete with the issue of ISO 9000:2000)

ISO 9004 – Guidance for performance improvement

The familiar 20 elements that form the structure of the ISO 9000:1994 series standards will be folded into a new structure with four main chapters:

- (1) Management responsibility.
- (2) Resource management.
- (3) Product and/or service realization.
- (4) Measurement, analysis, and improvement.

These four chapter topics describe the four phases of a fundamental concept of the new standards referred to as the Process Model. The concept of continual improvement is one of the additions to the old standard's requirements. The old Customer Complaint, Self-Audit, and Corrective and Preventive Action requirements were pointed in the direction of continual improvement, but now it will be a fundamental theme.

The ISO 9000:2000 standards include extension of customer awareness and concern beyond a customer complaint system to the requirement for actual measurement of customer satisfaction. The concept of customer satisfaction as a metric for quality system performance is a scoring criterion for the US Commerce Department's coveted Malcolm Baldrige National Quality Award for excellence in quality management and a standard feature of most modern quality management philosophies and paradigms.

The ISO 9000:2000 standard places more emphasis on the need to provide and make available specific types of resources. The required resources will include such elements as information, communication, infrastructure and work environment protection. The new standards have also been designed to be better aligned and compatible with ISO 14001.

If a company is currently certified to one of the existing ISO 9000 standards, particularly if the existing certification is to the soon-to-be obsolete 9002 or 9003

standard, then one should plan for an orderly transition to the new standards. If a company is planning to achieve ISO 9000 certification for the first time, the good news is that the new standards provide more flexibility for conformity. As a result, certification is more easily attainable than may have been possible under the old standards. In addition, service industry organizations will find the new standards much more easily applied to their business processes.

There is an important difference between the HACCP and ISO systems. HACCP is a tool for ensuring food safety whereas ISO is a tool for quality normalization. In other words, one can use HACCP to achieve a safe product while a HACCP system is managed using the ISO 9000 approach. Thus, ISO 9000 and HACCP systems are extremely compatible. Both systems emphasize error prevention through proper controls as opposed to detection of errors through final or customer inspection. Both require in-process controls, training and management commitment. However, in general ISO will require more documentation and record keeping than a HACCP system.

ISO 14001 is a similar set of standards that address environmental concerns, promoting a common approach to environmental management. In plain language, this means what an organization does to minimize harmful effects on the environment caused by its activities. It grew out of the Uruguay round of General Agreement on Tariffs and Trade (GATT) negotiations and the Rio Summit on the Environment (GATT, 1991). Similar to the ISO 9000 series of standards, ISO 14001 deals with the Environmental Management System (EMS) planned by a company. This EMS can be documented in an environmental manual, or maintained in sections of the company's quality or operations manual clearly stating the company's environmental goals. There is a good chance that with the next revision of these two standards systems, they will become one.

1.12 RELEVANCE OF HACCP TO SHRIMP CULTURE AND PROCESSING

While the relevance of HACCP is well recognized, its relevance to shrimp culture needs some elaboration. Dwindling marine resources are encouraging all nations to turn to aquaculture. Shrimp and prawn from aquaculture amounted to 41% of the total production in 1998 (FAO, 2000). This trend is constantly increasing with a high annual rate of growth. Tropical shrimp is presently farmed in over forty countries of the world producing over 68 000 metric tons (1.5 billion pounds) from over one million hectares, mostly in developing countries. Typically, the hazards associated with shrimp farming are residues of agrochemicals, veterinary drugs and heavy metal organic or inorganic contamination.

The wild and cultured shrimp resources of the US are limited due to climatic and economic factors. Shrimp, a major portion tropical in origin, is the second most consumed and popular seafood product. Its constant demand by the American consumer is met with imports in large quantities from the various shrimp producing regions mentioned above. Increased competition to meet high production targets and fight for market share has already resulted in the spread of disease in cultured animals, high mortality and decreased production in Taiwan and China. The dangers from adopting such an approach are the indiscriminate use of chemical and other

therapeutic agents such as antibiotics in shrimp culture. Aquaculture farms can be subject to pesticide and chemical run-off from adjacent land, depending on how that land is being used. When this occurs, the processor who purchases seafood from the aquaculture farm must make sure that the product does not contain pesticide residues in excess of FDA action levels for pesticides. The traditional approach to food safety assurance is end-product testing, but such an approach could become too expensive and difficult to control.

The fast paced developments in technology, medicine and communications have increased consumer sensitivity about healthy and safe food. Food produced with the help of the HACCP approach is known to have the best possible safety, because it is a system based on establishing preventive controls. HACCP application to shrimp culture and processing is both a relevant and crucial component for this globally traded product, and HACCP is the internationally recognized tool for assuring safety. When culture and processing of shrimp is done as an integrated operation, HACCP becomes all the more important. The other benefits of HACCP application include its use as a marketing tool; reduced destructive sampling of the finished product, as compared to the end-product sampling required under traditional inspection systems; and production and culture operations that are economical and cost-effective.

1.13 CURRENT WORLD STATUS OF HACCP IN SHRIMP CULTURE AND PROCESSING

The US, the EU, Canada and most of the major seafood producing countries that export seafood have already implemented or are in the process of adopting HACCP for their seafood industry. The factors in favor of HACCP are food safety concerns raised by the US domestic industry, support from domestic industries of various countries, and ongoing efforts by concerned international bodies such as the EU and the FAO to harmonize individual countries' inspection systems and requirements. The recommendations of the Codex Committee on Food Hygiene encourage the international use of the HACCP system.

Seafood is the most important food product exported by developing countries: it comes well before coffee, bananas and tea. For many developing countries, seafood trade is a significant source of foreign currency earnings. Net exports by these countries rose from US\$5.2 billion in 1985 to US\$17.2 billion in 1996 (FAO press release 98/38). Therefore, there has been an economic impetus to adopt HACCP by the developing countries. For example, in Asia, the application of HACCP in aquaculture is taking place particularly in the Association of South East Asian Nations (ASEAN) countries – Brunei, Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam. These countries received substantial assistance from the ASEAN–Canada Fisheries Post-Harvest Technology Project, which worked together with the government and industry of these countries in the design and implementation of the system. The technical approach observed in the HACCP plans reflects a multiple influence from Canada (QMP – Quality Management Program), the USA, Australia, New Zealand and Norway.

Thai efforts in the application of HACCP in shrimp aquaculture deserve special mention. In Thailand the Department of Fisheries, together with the aquaculture

and the processing industry, developed a National Quality Management program specifically designed to prevent and control drug, chemical residue and microbial contamination in farmed shrimp. The HACCP concept is being introduced into all operations, including shrimp production and handling at farm level.

In China, a number of actions are being taken by government and the aquaculture sector to promote the application of the HACCP system. HACCP is now applied in many fields, such as farming of shrimp, eels and bivalve shellfish (depuration stage). In Fujian, Hebei, Shandong and other provinces, there are about 20 companies engaged in aquaculture, and they have organized HACCP training programs. During 1996–7 HACCP was taught in a number of training activities organized by the Fishery Bureau of Ministry of Agriculture and NCQSTAP (National Center for Quality Standards and Testing of Aquatic Products). At the central government level, the new China Fishery Products Quality Certification Center, which was founded in 1997, also pays special attention to HACCP certification of aquaculture enterprises. In Vietnam, HACCP activities are strongly concentrated at seafood processing plant level, with the industry trying to comply with the pressure from the new fish importing sanitary regulations of the EU and USA. HACCP activities in aquaculture are very limited due to lack of interest and funds, because the industry and government assume that there is no pressure from importing countries for HACCP application. Many companies, particularly shrimp processing/ exporting companies, consider biological hazards at the plant reception stage for farmed raw material critical, but they monitor this step using a supplier's certificate, which is still an unreliable tool in Vietnam.

The Codex Alimentarius Commission (CAC) is an international organization jointly created in 1962 by the FAO and the World Health Organization (WHO) of the United Nations as a Food Standards Program. The CAC is comprised of five working groups. There are 25 committees within the five working groups. Issues relating to food safety that are also applicable to products from aquaculture fall under the general subject committees: 'Food Additives and Contaminants, Food Hygiene, Pesticide Residues, and Residues of Veterinary Drugs in Foods'. The purpose of CAC is to adopt international food standards in a uniform manner. These standards are aimed at protecting consumers and include all principal foods including aquaculture products. The Codex Committee on Food Hygiene has revised and adopted The International Code of Practice on General Principles of Food Hygiene (1993, 1997) which lays a firm foundation for ensuring food hygiene throughout the food chain, from primary production through to final consumption. It recommends a HACCP-based approach wherever possible. In addition, the Codex Committee on Fish and Fishery Products covers specific food safety issues, which includes the Draft Code of Hygienic Practice (FAO/WHO, 1998) for the products of aquaculture. This section of the code applies to industrialized and commercial aquaculture operations covering all stages of the aquaculture production cycle, from the selection of a site for establishing a farm, to grow out and primary on-farm handling of products.

Efforts are being made in different countries to translate HACCP-related material, making it available in local languages, e.g. Spanish and Vietnamese. For example, Vietnamese versions of US HACCP regulation and US HACCP training materials 21 Part 123 and Part 110 are available from the Seafood Export

and Quality Improvement Project (SEAQIP) and National Fisheries Inspection and Quality Assurance Center (NAFIQACEN), under the title *Qui che HACCP thuy san*.

A recent Dutch mission to Mexico observed that all fish processors and shrimp farmers contacted were fully aware of the need to establish quality control procedures in accordance with HACCP. Most of the larger companies now have qualified employees working solely on the implementation of HACCP. The following chapter describes how to assess and develop prerequisite programs that are necessary to provide a solid foundation for a HACCP system to be effective.

2 Implementing Sanitation and Related Programs as a Prerequisite to HACCP

2.1 INTRODUCTION

It is important to recognize that the HACCP system requires development, documentation and implementation of programs to control factors (such as sanitation) that are related to processing plant environment. These programs are called prerequisite programs: they are the foundation of a HACCP plan and need to be effectively controlled and monitored prior to the development of the plan. When proper sanitation procedures are in place, HACCP operates more effectively, because it is able to concentrate on the hazards associated with the food or processing, and not the processing plant environment. Prerequisite programs are being used formally as part of HACCP plans in some countries, e.g. the US and Canada, and can be defined as universal steps or procedures that control the environmental conditions within a processing facility that are favorable to the production of safe food.

The processing plant environment can be described in six broad areas:

- (A) *Premises*: Building and surroundings where the food is produced.
- (B) *Transportation and storage*: Receiving and storage of raw material, ingredients and packaging material.
- (C) *Equipment*: The design, installation and maintenance of all the equipment used in the production.
- (D) *Personnel*: The training of personnel in critical elements of manufacture and personal hygiene.
- (E) *Sanitation and pest control*: Sanitation procedures for equipment and facilities and pest control.

2.2 SANITATION, THE MOST IMPORTANT PREREQUISITE TO HACCP, AND WHAT IT ACTUALLY MEANS TO A PROCESSOR

Sanitation is the maintenance of a condition that is free from dirt and microbes such as bacteria while harvesting, handling and processing food; it aims to achieve conditions conducive to positive public health.

Meat from freshly harvested seafood is generally sterile, and their intestines in the natural state carry few of the types of microorganisms that are known to cause food poisoning. However, the different kinds of handling and processing involved between the catch and consumption expose the seafood to contamination. The environment is full of microorganisms that are present in soil, water, air, foods, humans and all animals.

As with most seafood, the major safety hazard associated with shrimp is microbial in nature. Once the microbes find their way on and into the seafood, they can grow more easily than in any other type of food, making seafood in general, and shrimp and other crustaceans in particular, highly perishable. A large proportion of the seafood is proteinaceous in nature. Seafood protein contains higher amounts of muscle protein and very little connective tissue protein. The high perishability of seafood is attributed to the muscle protein, which is more readily digestible than the more complex connective tissue protein. In addition, crustaceans have a high content of free amino acids, which are more readily utilized by the growing microbes.

After harvest shrimp is subjected to one or more steps, such as removing the head, peeling, icing, rinsing, etc., and is likely to become contaminated with spoilage and/or pathogenic microbes, unless proper sanitation measures are put into practice. The major thrust of sanitation quality assurance (QA) in shrimp culture, harvesting, handling and processing is geared towards preventing microbial contamination and controlling the growth of microbes.

2.3 WHAT ARE THE BENEFITS OF SANITATION?

The application of appropriate sanitation measures in conjunction with scientifically approved and time-tested processing methods results in a safe and wholesome product with a maximum shelf life, reduced spoilage and waste, reduced rejections and condemnations and increased profits to the processor.

2.4 REGULATORY REQUIREMENTS

The following federal regulations deal with sanitation in the United States:

- (1) Occupational Safety and Health Act (USDL, 1970) under the jurisdiction of the US Department of Labor. Additionally;
- (2) The Food and Drug Administration's (FDA's) Current Good Manufacturing Practices (CGMPs) in Manufacturing, Processing, Packing, or Holding Human Food (21 CFR, Part 110, 1981). These rules are further strengthened by the recent HACCP rules.
- (3) The HACCP regulations encourage, but do not require, that each processor develop a written sanitation operating procedure (SSOP) that is specific to each product produced at that location. The SSOP should describe how the processor would ensure compliance to sanitation practices under existing CGMPs. Sanitation controls may be included in a HACCP plan. In such a case separate SSOPs are not required. Whether or not a processor chooses to write an SSOP, the key sanitation conditions and practices relevant to the plant must be monitored. The purpose of the monitoring is to ensure that the requirements of the current GMP regulations are met. Monitoring must be done at sufficient (no definite requirement) frequencies to ensure that the current GMP requirements are met, particularly related to the following eight practices that fall under different prerequisite areas:
 - (a) Safety of the water used in processing.
 - (b) Food contact surfaces.

- (c) Prevention of cross-contamination.
- (d) Hand washing and sanitizing facilities.
- (e) Adulteration from lubricants, fuel, pesticides, etc.
- (f) Proper labeling, storage and use of toxic compounds.
- (g) Employee health and hygiene.
- (h) Pest control.

When the conditions and practices contained in the current GMP regulations are not met, they must be corrected in a timely manner. Records of the monitoring and the corrections must be kept. These records are subject to the same requirements as the HACCP records, except plant verification review.

If the product is imported, the importer must take affirmative action to ensure that the product imported is produced under the HACCP plan and sanitation controls that are equivalent to those required of domestic processors. Alternatively, assurances satisfactory to the USFDA shall exist such as an active Memorandum of Understanding (MOU) with the concerned exporting country as to the compliance to the HACCP regulations. In the absence of such assurances, the product in question will appear to be adulterated and will be denied entry into the US.

The Codex Alimentarius Commission (CAC) led to the acceptance of HACCP principles and The International Code of Practice on General Principles of Food Hygiene (1993, 1997) in the US. These principles lay a firm foundation for ensuring food hygiene throughout the food chain, from primary production through to final consumption.

2.5 HOW TO COMPLY WITH SANITATION REQUIREMENTS UNDER THE HACCP REGULATIONS

The first step involves a review of existing programs to verify that the prerequisite requirements are met and that all of the necessary controls and documentation are in place. Existing prerequisite programs are evaluated (for blank forms, see Appendix 1) for their conformance to the minimum requirements. The next step is to correct the identified deficiencies in the existing sanitation program. Sanitation is a prerequisite of HACCP; if provision is not adequate, additional steps will have to be included in the HACCP plan.

The general guidelines outlining the minimum criteria that are to be met in each of the prerequisite program areas of sanitation are described below.

2.5.1 Premises

Building and surroundings; sanitary facilities and quality of the water used in processing plant construction and layout.

Buildings and the surrounding areas

The selected *site* should be reasonably free from objectionable odors, smoke, dust or other contamination. The building(s) should be sufficient in size without crowding of equipment or personnel, well constructed and kept in good repair. They should be of such design and construction as to protect against the entrance and harboring of insects, birds or other vermin and to permit ready and adequate cleaning. The

ground should have an appropriate landscape that will not harbor animals. A grass free strip, 76.2–91.44 cm (30–36 inch) wide, should be located adjacent to the exterior walls. This strip should be covered with gravel to provide a barrier to rodents.

Floors should be constructed of durable, waterproof, nontoxic, nonabsorbent material, which is easy to clean and disinfect. The floors must have a 1/8 or 1/4 inch slope per foot to facilitate drainage. Floor coating systems that contain compounds providing antimicrobial capability in addition to physical wear and chemical resistance are now available. These compounds can also be used in coatings for walls and ceilings. Commercially available products in the North American market include 'Bioseal', a product of Palace Guard Inc., Alexandria, VA; 'Intersept' from General Polymers, Cincinnati, OH; and 'Quartzite' from Master Builders Technologies, Cleveland, OH.

Internal walls should be smooth, waterproof, resistant to fracture, light colored and readily cleanable. Acceptable materials for finishing inside walls are cement render, ceramic tiles, and various kinds of corrosion resistant metallic sheeting such as stainless steel or aluminum alloys. FRP (fiberglass reinforced paneling), plastic sheeting with adequate impact resistance and desirable surface qualities can also be used. Wall–floor junctions should be coved 2.54–7.62 cm (1–3 inch), and walls should be nonabsorbent, washable and damage resistant.

Drains should be of an adequate size and suitable type, equipped with deep seal (minimum of 7.62 cm or 3 inch) traps located appropriately, and with removable gratings to permit cleaning. In wet areas, one drainage outlet for each 37.16 m² (400 ft²) of floor space, and no more than 6.1 m (20 ft) apart is required. Drainage lines carrying waste effluent, except for open drains, should be properly vented, have a minimum internal diameter of 4 inches, and if required, run to a catch basin for removal of solid waste material. Such a basin should be located outside the processing area and should be constructed of waterproof concrete or other similar material, designed to the local specifications, and should meet the requirements of the official agency having jurisdiction. Walls should be free from projections and all pipes and cables should be sunk flush with the wall surface or neatly boxed in.

Windowsills should be made from smooth, waterproof material, and if wood should be well painted. They should be kept to a minimum size, be sloped inward at 45° and be at least 3 feet from the floor. Windows should be filled with whole panes and those that open should be screened. The screens (#16 mesh) should be made from suitable corrosion resistant material, easily removable and cleanable.

All *doors* through which product is moved should be at least 5 feet wide, made from material with a smooth and readily cleanable surface, and of self-closing type unless an air-curtain/screen is provided. Air curtains must comply with National Sanitation Standard #37 (ANSI/NSF, 1992) for Air Curtains for entranceways. If strip curtains are used, they must run the entire width of the opening with sufficient overlap of 1.3 cm (1/2 inch) between the flaps. An air curtain is intended to prevent flying insects from passing through an opening. It is not intended to exclude cats, dogs or other animals, or to replace a security door. Other uses include retention of cold or cooled air and containment of odors. Doors that provide staff access should be appropriately surfaced, at least on the processing side, to allow for ease of cleaning. Doors and windows should close tightly with a clearance not greater than 0.64 cm (1/4 inch) to exclude rodents and other crawling animals.

Ceilings should be at least 10 feet in height, free from cracks and open joints and should be of a smooth, waterproof, light colored finish. The idea is to prevent accumulation of dirt and condensation and the surface should be easy to clean.

Premises should be well ventilated to prevent excessive heat, condensation and contamination with obnoxious odors, dust, vapor or smoke. Airborne contamination is strongly suspected as the cause of some pathogenic contamination. Positive air pressure should be maintained with filtered HVAC (heating, venting and air conditioning) air flowing outward from the packaging area toward the building perimeter, 'from clean to dirty', to minimize entry of airborne microbes. The recommended conditions are: 40–60% relative humidity, 20–21°C (68–70°F) temperature, and a 0.85 m³/min (30 cfm) air-exchange rate. Ventilation openings should be screened and, if required, equipped with proper air filters. The screens must be of a mesh not larger than 0.06 cm (1/16 inch) to exclude insects.

A minimum illumination of 220 Lux (20 foot candles) should be provided in general working areas and 540 Lux (50 foot candles) at points requiring close examination of the finished product. Light bulbs and fixtures should be protected to prevent food contamination in case of breakage.

Sanitary facilities

Washrooms, lunch rooms and changing rooms

Toilet rooms should have walls and ceilings of a smooth, washable, light colored surface and floors constructed of impervious and readily cleanable material. Toilet facilities should be well lit, ventilated and well kept in a hygienic condition at all times. The doors leading to the toilet facilities should be of self-closing type and should not open directly into the processing area.

The adequacy of toilet facilities in relation to the number of employees can be assessed using the formula in Table 2.1.

Staff amenities consisting of lunchrooms, changing rooms, shower and washing facilities should be provided. Hand washing facilities should preferably be foot-operated and should have an adequate supply of hot and cold potable water or clean seawater and provided with liquid or powdered soap dispensers. Suitable hygienic means of drying the hands should be available.

A separate *refuse room* for storing waste in watertight containers or offal bins should be provided. The walls, floor and ceiling of such a storage room and the area under the elevated bins should be constructed of impervious material, which can be readily cleaned. Adequate precautions should be taken to protect the refuse against rodents, birds, insects and exposure to warm temperatures. Where waste material is held in containers outside the premises, the containers should be lidded. A separate

Table 2.1 Adequacy of toilet facilities

No. of employees	No. of toilets
1–9	1
10–24	2
25–49	3
50–100	5
For every 30 over 100	1

Table 2.2 Recommended chlorine concentrations

Use	Concentration (PPM as total residual Cl)
Washing product	2–10
Rinsing hands	50–100
Cleaning glazed surfaces	50–300
Cleaning smooth wood, metal or synthetic surfaces	300–500
Cleaning rough surfaces	1000–5000
Thaw/defrost	5.0–10.0

enclosure should be provided for their storage with easy access for vehicles loading and unloading. Stands for the containers should be of solid, hard and impervious material, which can be easily cleaned and properly drained.

Water quality

An ample supply of cold and hot at a minimum temperature of 82°C (180°F) potable and/or clean seawater at a pressure of no less than 1.4 kg/cm² (20 psi) should be available at numerous points throughout the premises at all times during the working hours. The cold water supply used for cleaning purposes should be fitted with an in-line sanitizer; for example, a system with a commonly used sanitizer such as chlorine allowing the residual chlorine content of the water to be varied at will in order to reduce and prevent the build-up of microorganisms. The residual free chlorine content (see Table 2.2) should be maintained at no more than the minimum effective level for the use intended.

Other sanitizers such as quarternary ammonium compounds, or quats, chlorine dioxide, ozonated water, etc., may also be used as per the instructions of the respective manufacturers’ recommendations.

Ice should be made from potable water or clean seawater and should be manufactured, handled and stored so as to protect it from contamination.

Non-potable water may be used for such purposes as producing steam, cooling heat exchangers and fire protection. Where a non-potable auxiliary water supply is used, the water should be stored in separate tanks and carried in separate lines, identified by contrasting colors and labeled, with no cross-connections or back-siphoning with the lines carrying potable waters.

All *plumbing and waste disposal lines*, including the sewer system, should be large enough to carry peak loads and should be approved for construction by the official agency having jurisdiction. Sumps or solid waste traps should preferably be located outside the processing area and so designed as to allow them to be emptied and cleaned at the end of each working day.

2.5.2 Transportation and storage (raw materials, ingredients and packaging materials)

Separate rooms with well-defined areas of adequate size should be provided for receiving and storing raw materials and for operations like peeling, washing, cooking, packing, breeding or freezing.

Separate storage facilities should be available for the proper dry storage of cartons, wrappings and other packaging materials in order to protect them from dust, moisture or other contamination.

Poisonous or harmful materials, including cleaning compounds, disinfectants and pesticides, should be stored in a separate room designed and marked specifically for the purpose.

Any byproduct plant should be entirely separate from the plant which is processing product for human consumption.

2.5.3 Equipment (design, installation and maintenance)

Equipment and utensils should be constructed of corrosion resistant materials. Food contact surfaces should be non-absorbent, nontoxic, smooth, free from pitting, unaffected by food and able to withstand repeated cleaning and sanitation. All stationary or heavy equipment that is difficult to move should be installed 1 foot away from the wall and 1 foot above the floor to facilitate easy cleaning, or be sealed to the floor.

Equipment should be maintained through appropriately frequent calibration of monitoring devices and equipment controls. A preventive maintenance program specifying the frequency of servicing of the equipment should be in place.

2.5.4 Personnel (training in manufacturing controls and hygienic practices)

The primary aspect of personnel training is to develop a program that provides (on an ongoing basis) the necessary instruction to production staff. First, training should be geared towards providing an understanding of the critical elements for which they are responsible, what those critical limits are, the importance of monitoring the limits and the action they must take if the limits are not met. Second, training in all aspects related to personal hygiene and hygienic handling of food should be given to all those who handle food. Third, training should include instruction in personal cleanliness and conduct.

2.5.5 Sanitation and pest control

Adequate sanitation procedures have to be developed for equipment, utensils, overhead structures, floors, walls, ceilings, drains, lighting devices, refrigeration units, etc., that directly affect the safety of the food produced in a facility. There should also be an adequate pest control program in place.

2.6 HOW TO DEVELOP SANITATION SSOPs TO COMPLY WITH THE PROPOSED HACCP-BASED REGULATIONS

Sanitation complements the efforts of HACCP-based inspection in achieving a safe and high quality product. Therefore sanitation, product safety and quality should be considered together as integral components in a plant's quality assurance program.

Recent deadly foodborne-disease outbreaks caused by *Listeria monocytogenes* and *Escherichia coli* O157:H7 have re-emphasized the importance of plant sanitation. New systems and components can help processors improve their procedures.

Like the HACCP plan, SSOPs must be plant specific. For example, Ecolab (St. Paul, MN) offers a computerized guide to SSOPs, which prepares and documents plant sanitation procedures (Morris, 1999). The system prepares preoperational SSOPs in accordance with government standards, references accepted cleaning practices, documents operational cleaning procedures and creates an SSOP monitoring and maintenance log.

Ecolab's Maxxum™ microprocessor-controlled cleaning and sanitation system can be reprogrammed to a plant's specific sanitation requirements. The system automatically custom-formulates the correct cleaning solution, in the correct quantity for each application and documents chemical use by cost and application. The operator can customize up to 174 different cleaning, sanitizing and detergent solutions from just eight concentrates, supplied in drums or bulk, without danger of manual exposure or spillage. An optional unit allocates acids. Compact, portable clean-in-place (CIP) systems can be less costly than fixed systems, but may not supply the volume and flow rates required to properly clean connected equipment.

Another example is a recent development that combines required cleaning capacity with minimum cost and floor space (Tri-Clover, Kenosha, WI). This Multiple Modular Operating Satellite System (MMOSS) can be stationed at strategic points in the process loop. Each satellite consists of a 159.41 (40 gal) and a 189.21 (50 gal) tank, two pumps, a heat exchanger, sanitary valves and related utilities and controls. Units require less than 3.25 m² (35 ft²) of floor space, are self-draining, self-cleaning and adaptable to SIP (steam-in-place). A single host unit supplies satellites with required solutions via individual loops. Satellites can operate independently to meet individual flow and rate demands. According to Tri-Clover, a MMOSS system saves water and utilities costs, and expands with plant expansion. Tri-Clover CIP and processing systems can now be monitored and controlled with Wonderware™, which graphically illustrates active systems, accesses current process data and documents historical data.

The following example illustrates the typical SSOPs in a seafood processing operation.

2.6.1 Cleaning schedule

Morning

Before operations start for the day, the shift quality supervisor inspects and verifies that all the equipment and plant area have been sufficiently detergent cleaned and sanitized. If anything has not been performed to his satisfaction, it will be re-cleaned and resanitized before the commencement of production. Chlorine is commonly used as a sanitizing agent in the seafood industry. All cleanser and sanitizing agent left from the previous clean-up must be removed.

Continuous cleaning

Tables, floors and other working surfaces should be sloped for continuous draining to avoid standing water in which bacteria multiply. Each tub/tote should be rinsed each time it is emptied.

Each rest break

All processing that has come onto the line should be completed and followed by the removal of all traces of the product; waste from the floor should be shoveled; and, for example, all working surfaces rinsed with water containing chlorine (5 PPM residual) or wiped/sprayed with alcohol.

Clean-up crews of one or two people should have staggered breaks, ensuring efficient cleaning operations and reduced overtime.

Lunch break

The processing line is cleared of all product; product should be re-iced; all waste should be shoveled; all working surfaces, wash tanks, tubs, carts and floors should be detergent cleaned and finally rinsed with a pressure hose using 25 PPM chlorine solution to lower any increase in the bacterial count. Before resumption of processing, all surfaces should be rinsed with 5 PPM chlorine solution to clean away excess chlorine.

End of the day

All of the steps mentioned above should be repeated. All machinery is broken down at the end of the production day. All equipment is hosed down with water to remove any loose debris. Scrapers, squeegees, sponges and brushes are important clean-up tools. The working surfaces are scrubbed with cleanser and a scrub brush, or any other alternate methods as available.

All floors and walls should be scrubbed down with a stiff bristle brush and/or a hose with a high-pressure low volume system with nozzle pressures up to 1000 psi. The working surfaces should be re-rinsed with a 30–50 PPM chlorine solution allowing at least 10 min contact time, followed by a final rinse with clean water or a 5 PPM chlorine solution, if allowed. This final low-level chlorine rinse will help prevent any corrosion of metal surfaces.

All the storage areas are swept every night after the end of production.

End of the week

Foam with alkali detergents is used for areas with hard deposits, so as to remove oil and proteins.

All loose materials are rinsed away. Detergents are mixed in the tank following the manufacturer's recommendations. Areas with heavy deposits of static material are sprayed with an alkaline detergent and allowed to soak for 30–60 min followed by a thorough rinse. All compounds used will conform to either EPA requirements or can be found in the USDA's List of Proprietary Substances and Nonfood Compounds (USDA, 1996). It may be also be necessary to use an acid detergent several times during the season. Acid detergents are used to remove mineral deposits and should not be used on concrete floors as they pit the concrete. All surfaces are steam cleaned once every week, wherever steam is available.

Microbiological counts using Rapid Microbial Detection, RMD (see Chapter 7 for details) techniques will be performed on the equipment surfaces to verify the effectiveness of the cleaning of the facility by the shift quality supervisor. These results will be used to guide the sanitation crew on areas for improvement.

End of the month

The ice room and refrigerated storage areas are emptied and cleaned using the alkaline detergent and chlorinated as described above.

End of three months

All machinery, tanks, tables, floors, walls and ceilings should be cleaned thoroughly to remove any accumulated dirt and bacteria.

All working surfaces are sanitized with a 25 PPM chlorine solution. In addition, all maintenance tools must be cleaned or replaced as needed.

2.6.2 Wash facilities

Foot-operated sinks are provided with soap dispensers and sanitizing solution of appropriate strength, in the production area.

2.6.3 Personnel

Employees are instructed to sanitize their hands in the following manner:

- (1) At the beginning of each day.
- (2) Prior to each break.
- (3) Each time they return after break.
- (4) At any time when they contaminate their hands. Contamination may be due to touching bare human body parts, coughing, sneezing, using a handkerchief or disposable tissue and handling soiled equipment or utensils.

Hair restraints must be worn at all times by everyone entering production areas. Employees are not allowed to wear any loose jewelry in the production and storage areas. Clean outer garments are provided to the employees twice every week and the soiled garments are scheduled for pick-up and cleaning at the same time. No eating, chewing or use of any tobacco is permitted in the production or storage areas.

2.6.4 Restrooms

All restrooms are cleaned nightly and an adequate supply of water, paper towels, soap, etc., will be replenished for the next day's use.

2.6.5 Water supply

The facility uses the municipal water supply supplemented by well water stored in overhead tanks. The overhead tanks are cleaned and sanitized once every month as described above.

2.6.6 Waste disposal

All processing wastes collected must be removed and properly disposed of when the receptacles are full.

2.6.7 Chemicals

All chemicals used in the facility are kept locked in the chemical storage room which is accessible to designated personnel only.

2.6.8 Pest control

There must be no pests in any area of a food plant because they are potential sources of contamination of food with foreign material, filth and bacteria.

SSOPs should include information such as a list of persons responsible and the frequency with which to perform each specific procedure; and establish monitoring procedures including person(s) responsible for monitoring and its frequency.

2.6.9 Records

The HACCP regulations include the following requirements to demonstrate the compliance of SSOP objectives mentioned above in sections 2.6.1–2.6.8.

- (1) The entire facility will be monitored and observations documented in the Daily Sanitation Report (see Appendix 2). This is required to ensure that each sanitation procedure is performed with requisite frequency.
- (2) All deviations from the requirements shall be noted, and appropriate corrective actions shall be taken and documented on the sanitation control record.

3 Developing a HACCP Plan

3.1 WHAT MUST BE IN A HACCP PLAN AND HOW TO IMPLEMENT A HACCP-BASED SYSTEM

Once the prerequisite programs that concentrate on the plant environment are in place, adequate and effective, the next step is to build HACCP into the system. HACCP concentrates on the hazards associated with the food and/or processing. The most crucial component of an effective HACCP plan is the commitment of the management to see through its effective implementation. There are several sequential steps involved in developing a HACCP plan. The plan itself is a written quality document which is based on the principles of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure. (Process means one or more actions or operations to harvest, produce, store, handle, distribute or sell a product or group of similar products.)

Although HACCP requires that a product-specific plan is required for each location of operation, such a practice is rarely carried out except in businesses with only one product line, such as shrimp processing. A single HACCP plan may include different kinds of fish and fishery products or production methods, or more typically a series of modules, if they have identical food safety hazards, critical control points, critical limits, raw material, ingredients, process operation, packaging, storage and distribution considerations. This chapter provides general guidelines in developing a HACCP plan specific to a given processor/product.

Examples that can be used for the development of a HACCP plan can be found in Appendix 3.

The regulation requires that an individual trained in HACCP develop the HACCP plan. Processors can use a trained employee or a trained third party. Pre-existing templates are available from a variety of sources including the Internet. The plan involves a total of 13 steps in the sequence given below. The first six are considered as preliminary steps (3.1.1–3.1.6), followed by the seven principles of HACCP (3.2.1–3.2.7).

3.1.1 Assembling a HACCP team and assigning responsibilities (*Form #1 in Appendix 3*)

The team should include members from various disciplines such as maintenance, production, sanitation, quality control, etc., since this brings expertise from all areas together in the development of the HACCP plan. The team members are required to have the knowledge and the authority to implement changes and be effective communicators. The primary goal of the team is to develop each step of the HACCP plan.

When selecting the team, one should focus on:

- those who will be involved in hazard identification;
- those who will be involved in the determination of critical control points (CCPs);
- those who will monitor CCPs;
- those who verify operations at CCPs;
- those who will examine samples and perform verification procedures.

Selected personnel should have a basic education and/or training in:

- the technology/equipment used on the processing lines;
- the practical aspects of food operations;
- the flow and technology of processes;
- applied aspects of food ecology, microbiology, chemistry, biochemistry, technology; and
- HACCP principles and techniques.

3.1.2 Developing an organizational chart and narrative (*Form #2 in Appendix 3*)

The team should prepare an organizational chart demonstrating the managerial responsibility of the firm and showing the chain of command within the management of the facility. The organizational chart is recommended even though it is not absolutely required by the regulations. The credentials, qualifications and professional certifications of the production and quality control personnel should also be part of the narrative. If a consulting laboratory does sampling and analysis, its official/professional accreditation documents should become part of the narrative. The team must identify and assign responsibilities for the personnel to implement the HACCP-based principles, directives and strategies during the operation.

3.1.3 Describing the intended use of the end product and its distribution (*Form #3 in Appendix 3*)

A complete description of each food product must be drafted by the HACCP team to assist in the identification of possible hazards that may be inherent either in the ingredients or in the packaging materials used in the formulation of the product. It is important that the team is familiar with the product properties, destination and usage. It is important, for example, to take into consideration whether sensitive segments of the population may consume the product in the form in which it leaves the processing plant. The description should include:

- Product names (common name) or group of product names (the grouping of like products is acceptable as long as all hazards are addressed).
- Important end-product characteristics – properties or characteristics of the food under review, which are required to ensure its safety (i.e. water activity, pH, preservatives).

- How it is to be used (ready-to-eat, for further processing, heated prior to consumption).
- Type of package, including packaging material and packaging conditions (normal/modified atmosphere).
- Shelf life, including storage temperature/humidity.
- Where it will be sold (retail, institutions, further processing).
- Labeling instructions (handling and usage instructions).
- Special distribution control (shipping conditions).

The intended use is the expected use by the targeted consumer. The product may be distributed directly in its original container; repackaged in consumer packs; or subjected to reprocessing by the importer such as cooking, breading, etc. The targeted consumer should be identified, in this case, an average retail customer and his/her family.

3.1.4 Identifying product ingredients and incoming materials (*Form #4 in Appendix 3*)

List the product ingredients and incoming materials (including raw materials, product ingredients, processing aids and packaging materials) that are used during the manufacturing process. This exhaustive listing is required to properly identify all potential hazards that could apply.

3.1.5 Developing an operational flowchart depicting the control points of a process in question (*Form #5 in Appendix 3*)

The process flow diagram will identify the important process steps (from receiving to final shipping) used in the production of the specific product being assessed. A process flow diagram must be constructed following interviews, observations of operations, and other sources of information such as blueprints. There has to be enough detail to be useful in hazard identification, but not so much as to overburden the plan with less important points.

3.1.6 Developing a plant schematic (*Form #6 in Appendix 3*)

A plant schematic should be developed to show product flow and employee traffic patterns within the plant for that specific product. The diagram should include the flow of all ingredients and packaging materials from the moment they are received at the plant, through storage, preparation, processing and packaging, to finished product holding and shipping. The personnel flow should indicate employee movement through the plant, including changing rooms, washrooms and lunchrooms. The location of hand wash facilities and foot baths (if applicable) should also be noted. This plan should aid in the identification of any areas of potential cross-contamination within the establishment.

Once the process flow diagram and plant schematic have been drafted, they must be verified by an on-site inspection for accuracy and completeness. This will ensure that all the major process steps have been identified. It will also validate the assumptions made with respect to the movement of product and employees in the premises.

3.2 DEVELOPING A HAZARD ANALYSIS (HA) WORKSHEET FOLLOWING THE SEVEN PRINCIPLES OF HACCP (Form #7 in Appendix 3)

The HA worksheet is developed following the seven principles of HACCP as described below.

The National Academy of Sciences (NAS) convened the National Advisory Committee for Microbiological Criteria for Foods (NACMCF), an independent panel of food safety experts, at the request of the federal food inspection agencies. The committee first met in November 1989 to prepare a draft working report prepared by a HACCP working group of the Codex Committee on Food Hygiene. The committee's HACCP working group met again in July 1991 to review its 1989 draft. Based upon its review, the committee made the determination to expand its draft report by emphasizing the concept of prevention, incorporating the CCP decision tree to facilitate the identification of critical control points and providing a more detailed explanation of the application of HACCP principles to achieve food safety. In Europe, the European Community issued Directive 93/43 (EC, 1993) on the hygiene of foodstuffs. It lists the first six principles required to develop the system of HACCP and can be interpreted in virtually the same way as Codex or NAMCF, with the exception of any specific reference to record keeping. The NACMCF's HACCP working group reconvened in 1995 and made the HACCP principles more concise, revised and added definitions, included sections on prerequisite programs, education and training and implementation and maintenance of the HACCP plan, and once again endorsed HACCP as an effective and rational means of assuring food safety from harvest to consumption (NACMCF, 1997).

3.2.1 First principle of HACCP – identify potential hazards and appropriate preventive measures

Hazard may be defined as any *biological, chemical or physical property* of the food that may cause an unacceptable consumer health risk if not controlled. Set up the HA worksheet and record each of the processing steps (taken from the process flow diagram *Form #5* in Appendix 3) in Column #1. Identify potential species and process related hazards associated with each step of the process, ingredients, etc., and list them in Column #2. This information can be obtained from technical experts, Government publications such as the *HACCP Training Manual (with models)* by Seafood HACCP Alliance (1998), *FDA Fish and Fishery Products Hazards and Controls Guide* (1998), *A Compendium of Fishery Product Processing Methods, Hazards and Controls of Seafood HACCP Alliance* (1999), *Codex Alimentarius* (1998) or technical journals.

Some of the common contaminants in seafood and their control measures are described below. Seafood hazards are usually classified into biological, chemical and physical categories.

- (1) Biological hazards: Microbial pathogens such as bacteria, viruses and parasites.
 - (a) *Bacteria*: These are prokaryotic, unicellular, microscopic organisms, ubiquitous in distribution, found in every environment and able to adapt to

almost every growth condition. Like all living things they require water and nutrients for their survival and growth.

The presence of bacteria in foods is potentially hazardous not only because some kinds are pathogenic, but also because others can increase spoilage rates, resulting in unwholesome products. The pathogenic kinds of bacteria produce or contain toxins which cause illness when released into the food or the human system. The resulting illness can have a range of effects from minor to lethal on humans and animals.

The pathogenic bacteria release toxins into the substrate, which can be a food product or the human gastrointestinal system. The resulting illnesses are then categorized as intoxications or infections.

- (i) *Intoxication*: Occurs when a person ingests food that contains toxins already formed in it due to bacterial growth. Examples are *Staphylococcus aureus* (toxin causing diarrhea and/or vomiting) or *Clostridium botulinum* (neurotoxin causing paralysis).
- (ii) *Infection*: Live cells or viable spores of a pathogen must be ingested and grow inside the body. These infections can be *invasive* or *noninvasive*.

Invasive are those types of bacteria that attack the mucosal linings, resulting in tissue destruction. Pathogens can also invade underlying cells, other tissues, or cells associated with the immune system. Examples of invasive type pathogens are *Salmonella*, *Listeria monocytogenes*, *Shigella*, some types of *Escherichia coli*, *Yersinia* and *Campylobacter*.

Noninvasive are those types of bacteria, usually enterotoxigenic, that produce toxins in the intestinal tract. This type of infection is caused by the attachment of the ingested bacteria to the small intestine, and toxin is then released into the intestinal tract. Examples of noninvasive pathogens are *Vibrio cholera*, *V. parahemolyticus*, some types of *E. coli*, *Bacillus cereus* and *Clostridium perfringens*.

Control measures: Good sanitation practices; thermal processing to 100°C internal temperatures, where applicable; proper chlorine concentrations and time of contact; freeze-drying; and ultraviolet radiation. Partial inactivation due to food processing operations such as freezing, spray drying, acid, sulfites or ascorbates in foods.

- (b) *Viruses*: Viruses are submicroscopic intracellular parasites and are not complete cells. Viruses can enter the food supply in several ways, such as through flies, roaches and infected food handlers or through sewage. The hepatitis group (A, non-A and non-B hepatitis) and Norwalk group are the two most important types of viruses implicated in seafood-borne or waterborne infections.

The term hepatitis A (HAV) or Type A viral hepatitis replaces all previous terms: infectious hepatitis, epidemic jaundice, catarrhal jaundice, Botkin's disease and MS-1 hepatitis. HAV is endemic throughout much of the world. It is excreted in the feces of infected person and can produce clinical disease when susceptible individuals consume contaminated water or foods handled by infected workers.

The virus has not been isolated from any food associated with an outbreak. No satisfactory method is presently available for routine analysis of

food, but sensitive molecular methods used to detect HAV in water and clinical specimens should prove useful to detect the virus in foods. Among these, the polymerase chain reaction (PCR) amplification techniques seem particularly promising.

The common names of illnesses caused by the Norwalk and Norwalk-like viruses are viral gastroenteritis, acute nonbacterial gastroenteritis, food poisoning and food infection. The fecal–oral route through contaminated water and foods also transmits these types of viruses.

Control measures: Good sanitation practices; thermal processing to 100°C internal temperatures, where applicable; proper chlorine concentrations and time of contact; freeze-drying; and ultraviolet radiation. Partial inactivation due to food processing operations such as freezing, spray drying, acid, sulfites or ascorbates in foods.

- (c) *Parasites:* Parasites are known to be a potential problem in shrimp.

Control measures: Physical removal by candling; avoiding consumption of raw or undercooked food; blast freezing to –35°C or below for 15 h; frozen storage to –23°C or below for 7 days; cooking to internal temperatures of 100°C.

- (2) **Chemical:** A chemical hazard is a substance found in the food that is either poisonous or deleterious; these are classified either as natural, or as due to human intervention causing intentional or unintentional addition to the food product.

- (a) *Natural chemicals* are those found in the environment. Toxins of a chemical/biochemical nature in seafood include scrombrotoxin, ciguatoxin, shellfish toxins (paralytic shellfish toxin, domoic acid or amnesic shellfish toxin, diarrhetic shellfish toxin) and mercury. None of the natural toxins have been known to cause a potential problem in shrimp.

- (b) *Human intervention:* Chemicals used in agriculture and the chemical industry, if used near aquaculture operations, could be a potential problem: polychlorinated biphenyls (PCBs); other chlorinated hydrocarbons; pesticides, herbicides, rodenticides, such as aldrin, dieldrin, chlordane, endrin, heptachlor, heptachlor epoxide, chlordecone, DDT, Toxaphene, etc.; antibiotics; mercury; sanitizers; cleaners; lubricants, etc.

Control measures: Site survey; monitoring present land-use practices in the area immediately surrounding the production area; delayed harvest; grower's certification by lot/site to ensure the product is free from chemical contamination and drug residues; use of FDA-approved chemicals and drugs; soil and water testing; training the personnel in soil and water chemistry and shrimp culture; periodical testing of the product for chemicals and drug residues.

- (3) **Physical hazards:** Any material in the food that is not normally associated with it is considered as foreign material. Examples of physical hazards include glass, wood, staples, insect fragments, rodent filth, personal effects such as jewelry, band-aids, cigarette butts, etc.

The next step is assessing the significance of the risks posed by a given hazard. A hazard is considered significant at any processing step where a control measure

is, or can be used to prevent, or eliminate (or reduce to an acceptable level) unsafe levels of contaminant(s) that are reasonably likely to occur.

Determine if the identified potential hazard(s) is significant. HACCP focuses solely on significant hazards that are reasonably likely to result in an unacceptable health risk to the consumer. The criterion that determines the significance of a hazard is asking yourself, for example, 'Is it reasonably likely that unsafe levels of environmental chemical contaminants or pesticides will be introduced in the grow-out ponds?' Environmental chemical contamination and pesticides could be considered a significant hazard with respect to cultured shrimp if the surrounding area is used for agricultural purposes. Once it is determined, transfer it to Column #3 of the HA worksheet as YES.

Justify your decision for Column #3 and write in Column #4, giving proper reason(s), and proceed to the next identified hazard; industrial, municipal and agricultural pollution of soil and water depending on land use in the immediately surrounding areas.

List appropriate control measures in column #5 of the HA worksheet. For example, see HA worksheet *Form #7a*. The technical information can be obtained from FDA literature and other sources, as shown in the first paragraph of this section.

3.2.2 Second principle of HACCP – determine critical control points (CCPs) (For example, use the HACCP decision tree for interpretation and report in the CCP determination worksheet) (*Form #8* in Appendix 3)

A CCP is defined as a point, step or procedure where a food safety hazard can be prevented, eliminated or reduced.

Examples of CCPs may include but are not limited to chilling, cooking, prevention of cross-contamination and certain aspects of employee and environmental hygiene.

CCP determination has to be made for each potentially significant hazard identified and noted in Column #3 of the HA worksheet (*Form #7*). CCP determination is made with the help of a '*CCP decision tree*' (see Fig. 3.1). The decision tree incorporates the four questions of the NACMCF decision tree (1997). The decision tree results are reported in the CCP determination worksheet.

The first column of the CCP determination worksheet identifies the Process step/Incoming materials where a hazard(s) has been identified. In the second column, identify the category of the hazard (biological, chemical or physical, with a B, C or P notation) related to each Process step/Incoming materials and describe concisely the identified hazard(s). If the identified hazard is determined to be fully controlled, write in that column and proceed to the next identified hazard. If the identified hazard is not fully controlled by a prerequisite program, then proceed to Question 1 (Q1) in the next column.

Question #1

Do control measure(s) exist for the identified hazard?

Question 1 should be interpreted as whether or not the operator could use a control measure at this step or anywhere else in the establishment to control the identified hazard. Examples could include contamination from sewage, industrial

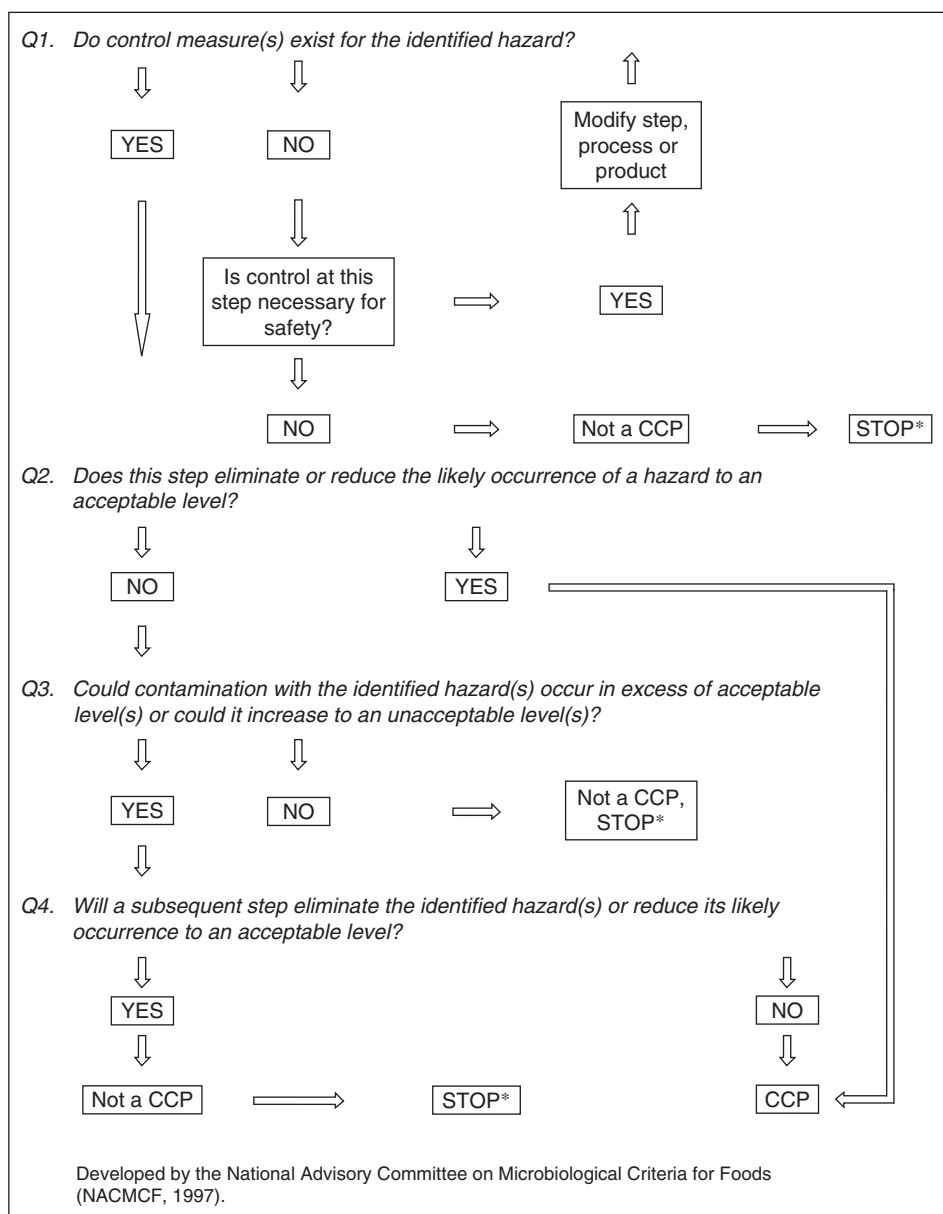


Fig. 3.1 Example of a CCP decision tree.

chemicals, pesticides and herbicides, etc., of the farm water during the site selection and preparation stage of shrimp culture.

- If the response to Question 1 is yes, proceed to the next question in the decision tree. The control measures include selecting a site free from all sources of potential industrial, municipal and agricultural pollution.

- If answer to Question 1 is no, determine if the control at this step is necessary for safety. If no, go to Question 2. If yes, modify the process and go back to Question 1.
- In this example, the answer to Question 1 is yes. Therefore, proceed to the next question.

Question #2

Does this step eliminate or reduce the likely occurrence of a hazard to an acceptable level?

- In the above example, the contaminants from sewage, agricultural and industrial pollutants can vary depending on the future runoff from excessive rainfall and the answer is no. Therefore, proceed to Question 3.
- On the other hand, if the answer to the above question is determined to be yes, this step will then be considered as a CCP.

Question #3

Could contamination with the identified hazard(s) occur in excess of acceptable level(s) or could it increase to an unacceptable level(s)?

- If the answer to this question is no, the step is not a CCP. Stop this analysis at this point and continue the analysis with other hazards.
- If the answer is yes, as in this case, proceed to Question 4. The contamination from sewage, agricultural and industrial pollution can vary depending on the season and rainfall and therefore may reach unacceptable levels.

Question #4

Will a subsequent step eliminate the identified hazard(s) or reduce its likely occurrence to an acceptable level?

- The answer to this question is no, since environmental contaminants due to runoff cannot be eliminated. Therefore the process step 'Site selection and preparation' becomes a CCP.
- If the answer is determined to be yes, such as providing improved drainage, moving the sources of contamination away from the site, etc., this will not be a CCP and further analysis of other hazards could be considered.

The last column in *Form #8* is where CCPs are identified. CCPs should be identified numerically with a category qualifier 'B', 'P' or 'C' for biological, physical and chemical. For example, if the first CCP identified will control a biological hazard, it will be recorded as CCP-1B. If the second CCP identified will control a chemical hazard, it will be recorded as CCP-2C. If a biological and a chemical hazard are controlled at the same processing step, and this is the fifth CCP, then the CCP number used will be CCP-5BC. This identification protocol was developed to sequentially identify CCPs independent from process step numbering and readily inform the user of the HACCP model of which type(s) of hazard needs to be controlled at a particular process step.

Having now established the CCPs, the next step is to report CCPs as YES or NO in Column 6 of *Form #7*, the HA worksheet.

HACCP principles 3–7 will lead to the development of a HACCP plan that is described on *Form #9* in Appendix 3. The critical limits, monitoring procedures, deviation procedures, verification procedures and record keeping will be described in a firm's HACCP plan. This HACCP plan will provide the written guidelines that will be followed in an establishment.

Transpose only those CCP(s) identified as YES and the corresponding significant hazards from the HA worksheet to Columns #1 and #2 of the HACCP plan form (*Form #9* in Appendix 3).

3.2.3 Third principle of HACCP – establish critical limits (CLs)

CLs are defined as the criteria that must be met for each control measure associated with a CCP. CLs need to be set for each control measure. They are values which separate acceptability from unacceptability. These parameters, if maintained within boundaries, will confirm the safety of the product.

The CLs should meet government regulations, company standards or other scientific data. CL information can be obtained from published sources such as scientific journals, the Internet, Codex, ICMSE, FDA, USDA guidelines, expert advice from consultants and experimental data. Once the critical limits are established, write them in Column #3 of *Form #9* together with the description of the process step, the CCP number and hazard description.

Some examples of CLs for preventive measures are:

- (1) In the receiving step of cultured shrimp, where 'environmental chemical contaminants and pesticides' is determined as a CCP in the HACCP plan form. In this case, determine, using appropriate methods, the maximum and minimum values to which a feature of the process must be controlled in order to prevent the hazard. In the above example, if supplier's certification is chosen as a control measure, the CL could be as follows:

A certificate accompanying all lots received indicating that the fish were harvested from waters free from the environmental contaminants and pesticides of concern and that the levels of those pesticides and contaminants in the fish flesh are below the established tolerances, action levels or guidance levels.

- (2) If soil and water testing and land use monitoring is chosen as a control measure, the CL could be as follows:

Results of analysis of the flesh for each delivery using accepted sampling procedures for specific chemical contaminants and pesticides must not exceed the established tolerances, action levels or guidance levels. Annual reports from all suppliers that show that agricultural and industrial practices in the area immediately surrounding the production area are not likely to cause contamination of the shrimp above the established tolerances, action levels or guidance levels.

3.2.4 Fourth principle of HACCP – establish monitoring procedures (MPs)

Monitoring is a planned sequence of observations or measurements which may be either qualitative or numeric to assess whether a CCP is under control, and to produce an accurate record for future use in verification. Examples of measurements

for monitoring include physical aspects such as visual observations, sensory analyses, chemical, microbiological indices, temperature, time, pH, moisture level, etc.

Monitoring requires knowledge in sampling, based on appropriate statistical procedures. (For a discussion on sampling, see Chapter 5.) When analyses are done, approved test protocols (Association of Official Analytical Chemists, AOAC, USDA, FDA, EPA or other relevant agencies) must be applied. The monitored data may be collected manually or through automation. Recent developments in microprocessing systems incorporate visual and/or sound alarms when critical limits are exceeded. If calibrated and maintained correctly, automated systems can help reduce the human error.

Monitoring serves three main purposes:

- (1) It enables tracking of the system's operation. If monitoring indicates that there is a trend towards loss of control, then corrective action can be taken to bring the process back under control before a deviation occurs.
- (2) It is used to determine when there is loss of control and a deviation occurs at a CCP, that is, exceeding the critical limit.
- (3) It provides a written documentation for use in verification of the HACCP plan.

At each CCP, the monitoring requirements and the means to ensure that the CCP remains within the critical limits are specified. Monitoring procedures generally relate to on-line processes and are rapid type tests, visual monitoring of documentation (for example, product certification) or any other appropriate procedure. For each CCP identified in Column #1 of the HACCP plan form, monitoring activities must be filled from Column 4A to 4D with information about:

- (1) What will be monitored?
- (2) How will it be monitored?
- (3) Frequency of monitoring; and
- (4) Who will perform the monitoring?

That is the person(s) responsible for carrying out the testing. It is recommended that the testing procedures for each monitoring activity are also specified.

Those individuals monitoring CCPs must:

- (1) be trained in the technique(s) used to monitor each control measure;
- (2) fully understand the purpose and importance of monitoring;
- (3) have ready access to the monitoring activity;
- (4) be unbiased in monitoring and reporting; and
- (5) accurately report the monitoring activity;
- (6) report unusual occurrences immediately so that adjustments can be made in a timely manner to assure that the process remains under control;
- (7) report a process or product that does not meet critical limits so that immediate corrective action can be taken.

All operational records and documents that are associated with CCP monitoring must be properly filled in and signed by the person doing the monitoring and verified (signed) by a responsible official of the company.

3.2.5 Fifth principle of HACCP – set corrective action (CA) protocols to deviations

The HACCP system of food safety management is designed to identify potential health hazards and to establish strategies to prevent their occurrence. However, ideal circumstances do not always exist. When deviation occurs, corrective action plans must be in place:

- (1) To identify the product that was produced during the process deviation and determine its disposition.
- (2) To correct or eliminate the cause of the deviation and restore process control.
- (3) To maintain fully documented records of CAs.
- (4) If predetermined, CA procedures are to be documented in the HACCP plan form Column #5.
- (5) To perform or obtain timely a reassessment by an HACCP-trained individual to determine and modify the HACCP plan so as to reduce the risk of recurrence of the deviation.

A deviation is defined as failure to meet the specified critical limits. All deviations must be corrected by taking appropriate CA(s) to control the noncompliant product and to correct the cause of such noncompliance. CA procedures may be predetermined and documented, or processors may choose not to predetermine their CAs. In such a case, the affected product must be segregated and held until the product safety is determined by individual(s) who have a thorough understanding and training in food safety, HACCP process, product and plan.

A predetermined CA must describe the acceptable procedure for a given deviation. The diversity of possible deviations at each CCP means that more than one corrective action may be necessary at each CCP. The corrective action(s) must correct the cause of the deviation and must control the actual or potential hazard resulting from the deviation. Product control includes proper identification and handling of the affected lots.

3.2.6 Sixth principle of HACCP – establish verification procedures

Each HACCP plan should include procedures and their scheduled frequency for verifying individual CCPs and for the overall plan. The verification procedures at each CCP are written in Column #6 of the HACCP plan form.

The NACMCF (1997) and Codex systems tend to simplify the verification procedures and are similar. Verification activities differ from monitoring activities. Verification procedures mean steps that are taken to ensure that the HACCP plan is effective. They include:

- (1) On-site verification, for example, verifying the product flowchart or checking that processes are operating within established critical limits.
- (2) Record review verification such as reviewing consumer complaints and calibration records.

- (3) Targeted sampling and testing such as reviewing CCP monitoring and CA records, in-process and end-product testing records or checking vendor compliance when receipt of material is a CCP and purchase specifications are relied on as critical limits.
- (4) Implementation of verification procedures where the product is imported from countries without a Memorandum of Understanding (MOU).

Such verification procedures include (1) product specifications that comply with the FD&C Act assuring safety and (2) affirmative steps by the importer such as obtaining a foreign processor's HACCP plan, monitoring records for the lot being entered, written guarantee that the regulation is being met, or performing other verification procedures that provide equal levels of assurance.

Some specific examples of verification procedures:

- (1) Checking each incoming lot monitors the acceptability of frozen shrimp free from *Salmonella*. The certificate of guarantee from the manufacturer is examined by the raw material receiver to ensure the shrimp meet the critical limits set (in this instance, *Salmonella*-free).
- (2) Verification of the monitoring activity involves an audit of the supplier's *Salmonella*-free claim by having a sample analyzed at a private laboratory. A private laboratory for *Salmonella* tests a sample of shrimp from every tenth load.
- (3) Monthly thermometer check/calibration at the cooking process of shrimp to validate the accuracy of the indicating thermometers.
- (4) The monitoring by the foreman of the cleanliness of equipment and utensils in the post-cooking area is done on an hourly basis. The quality control personnel verify the monitoring activity through unexpected audits. The quality control personnel swab the product contact surfaces and carry out microbiological testing to determine the microbiological cleanliness of the area.

Verification also includes another element, validation. It differs from monitoring, and is primarily focused on collecting and evaluating scientific and technical information pertaining to each CCP. This step is necessary to evaluate the techniques used and their effectiveness in controlling a particular hazard. The purpose is to determine whether the HACCP plan, when properly implemented, will effectively control all the identified hazards. (For example, whether the time and temperature used to hot-smoke salmon could effectively prevent *Clostridium botulinum* toxin formation in the finished product.)

In carrying out the verification activities, the establishment may find that some hazards were overlooked, or they may discover new or unexpected hazards. In this case, the plan needs to be modified appropriately. As part of the verification procedure, the HACCP plan must be reassessed at least once a year and whenever any changes occur that could affect the hazard analysis or HACCP plan in any way. An individual adequately trained in HACCP must perform this reassessment. Results from verification activities are not intended for use in making decisions on the acceptability of lots of product.

3.2.7 Seventh principle of HACCP – establish procedures for record keeping

Records are essential in determining the compliance of the establishment in following the agreed-upon HACCP plan. The HACCP records differ from the records that are kept to ensure compliance to the prerequisite program (sanitation) requirements. The required HACCP records to be kept at each CCP are written in Column #7 of the HACCP plan form.

Types of records needed:

- (1) The HACCP plan must be on file at the establishment. It is advisable (but not required) to maintain support documentation containing information and data used in developing the plan. The examples of support documentation include a list of the HACCP team, summary of the preliminary (six) steps, or scheduled process developed by a competent processing authority. Generally, records will be generated at each step of the development process that leads to an HACCP plan.
- (2) Records of CCP monitoring. Such records may include storage temperature, cooking time and temperature.
- (3) Records of deviations and corrective action taken.
- (4) Records of verification activities such as verification of the accuracy and calibration of all monitoring equipment, modifications to the HACCP plan periodic in-line and finished product microbiological, physical or chemical testing.
- (5) Sanitation control records.
- (6) Importer verification records.

All HACCP monitoring records should be on forms that contain the following information: form title; firm name; time and date; product identification (including type, package size, processing line and product code where applicable); actual observation/measurement; critical limits; operator's signature; reviewer's signature; and the date of review.

The monitoring and CA records should be reviewed daily, even though the regulations mandate one week from the date of recording. The records must be retained for one year for refrigerated products and two years for frozen products.

4 HACCP in Shrimp Processing

4.1 INTRODUCTION TO HACCP IN SHRIMP PROCESSING

4.1.1 Background

All shrimp are decapod crustaceans, with ten legs and external skeletons. Shrimp are harvested from cold (northern shrimp) or warm (tropical shrimp) brackish to marine environments. Freshwater shrimp is a further category, though not as large commercially as the other two. Most cold-water shrimp belong to the Pandalidae family. Tropical shrimp are usually called penaeids, since most common species are in the Penaeidae family. Freshwater shrimp is a subgroup that belongs mostly to the Palaemonidae family. The Food and Agriculture Organization (FAO) considers freshwater species 'prawns' and marine species 'shrimps'. Shrimp range in size and color. They are also sometimes grouped according to the natural color of their shells and are commonly referred to as whites, pinks, tigers (with stripes) or browns depending upon their physical appearance. The primary carotenoid substance astaxanthin controls the coloring in all species of shrimp and is more prominent in the pink shrimp, less in brown, and the least prominent in the white shrimp. The color varies widely according to species, location, what the shrimp eats and the environment from which it is caught. Pinks, for example, can vary from dark amber to a delicate light pink color, browns vary from light to dark brown and whites appear gray in their natural state. When peeled and cooked, meats from most shrimp look very similar.

About 60% of the world's shrimp is wild-caught and the remaining supply comes from aquaculture. Farm-raised shrimp comes from over 50, principally developing, countries around the globe. Since the product originates from such a diverse range of habitats, the microflora, toxins, chemicals, parasites and other potential hazards to which the shrimp are exposed before they are wild-caught/harvested, and exposure to chemicals while being processed, become critical in determining its safety for consumption. The international scientific community has agreed on the benefits of applying the principles of HACCP, a system based on establishing preventive controls for attaining food safety, to prevent or minimize health hazards.

4.1.2 Major cold-water shrimp species

Giant spot shrimp (*Pandalus platyceros*) are the largest of the commonly caught pandalids and are found on both sides of the North Pacific in moderate volume. They are highly regarded for their firmness and flavor. Pink shrimp (*Pandalus borealis* and *P. jordani*) are essentially the same in terms of texture and flavor. They are usually sold cooked and peeled in finished counts ranging from 250 to 300/lb. Sidestripe shrimp (*Pandalus dispar*) have white, lengthwise stripes on a pinkish red

shell. They are bigger than giant spots, firm textured and flavorful and are found from Alaska to Oregon.

4.1.3 Tropical shrimp species

Indian white shrimp (*Penaeus indicus*) are one of the major commercial species in the world industry. They are also found from eastern Africa to India, Indonesia and northern Australia. Banana prawns (*Penaeus merguensis*) are similar to Indian white shrimp (*Penaeus indicus*), except the shell is more yellow. This species is farmed in Thailand and harvested wild in the Philippines, Malaysia and Indonesia. Black tiger shrimp (*Penaeus monodon*) are farmed intensively in Thailand and Taiwan. They are also harvested wild throughout the Indo-Pacific area. They grow rapidly when cultured and can reach up to 13 inches in length. Blue shrimp (*Penaeus stylirostris*) have a firm texture and good flavor. The shells are bluish. They are found wild on the Pacific side of Mexico and are also farmed. They are also called Mexican whites or west coast whites. Brown shrimp (*Penaeus aztecus*), found from North Carolina to the Gulf of Mexico, are the most abundant and important species for Mexico and the US. Brown shrimp grow to large sizes and, depending on their origin, may have an iodine flavor. They have a firm texture and have a groove in the last tail segment that can be felt easily.

Central American white shrimp (*Penaeus occidentalis*) are medium sized with good flavor and texture. They are caught on the Pacific side of Central and South America. Chinese white shrimp (*Penaeus chinensis* and *P. orientalis*) are an important export product from China where they are farmed and harvested in the wild. Gulf pink shrimp (*Penaeus duorarum*), commercially important to the US and Mexico, are found along the southeastern US coast and through the Gulf, particularly on the Campeche banks. They are sweet and tender in texture. Gulf white shrimp (*Penaeus setiferus*) are caught from the Carolinas south to the Gulf of Mexico. Variations in shell color can cause them to be confused with brown shrimp caught in the same area. Unlike brown shrimp they do not have a groove in the last tail segment.

Indian brown shrimp (*Metapenaeus affinis*), produced by Pakistan, India, Malaysia and Hong Kong, has become important in world trade. Mexican brown shrimp (*Penaeus californiensis*) are the most common shrimp caught off Mexico's Pacific coast and are exported to the US and Japan in a wide variety of sizes and forms. Red-spotted shrimp (*Penaeus brasiliensis*) are very similar in appearance to Gulf pinks. Southern white shrimp (*Penaeus schmitti*) are virtually identical to Gulf whites. They are caught in the Caribbean off the coast of South America. Southern pink shrimp (*Penaeus notalis*), often called Brazil pinks, are similar in appearance to Gulf pinks. They are found from the Caribbean to southern Brazil and off West Africa. West coast white shrimp (*Penaeus vannamei*), also called whiteleg shrimp, are found wild on the Pacific side of Central and South America and are farmed in significant quantity in Ecuador and Central America. They account for a large volume of whites in the US marketplace.

4.1.4 Freshwater shrimp

Under this category are giant river prawns (*Macrobrachium rosenbergii*), which are harvested wild from northern Australia to India and are also farmed in several

countries. They grow to more than 1 foot in length in brackish rivers. The meat is mild and best when baked or broiled. These prawns are identifiable by size and by their long claws and dark blue shell.

4.1.5 Product/market forms and definitions

This information is useful when writing the purchase specifications as part of the HACCP. Raw, headless, shell-on shrimp, also known as *green headless*, are the most common form sold in the US and Japan. If harvested wild, most large shrimp have the heads removed on board. The ‘tails’, which are actually the abdomens, are then iced or frozen. Green headless shrimp is defined as the six tail segments of the shrimp, complete with shell, tail fin and vein (shrimp in shell without the head). The term *green* refers to fresh or raw, and does not indicate the color of the shrimp. White shrimp of the east and the Gulf coasts of the US have a greenish spot on the tail before cooking, and this may be the origin of the term.

The other common market forms are head-on (HO), headless (HL), peeled and undeveined (PUD – shrimp peeled, heads and shells removed, but not deveined). Most raw peeled and deveined (PD) shrimp is peeled round style with the tail shell removed. After the shell is removed, a shallow cut is made down the back to facilitate the complete removal of the sand vein. Other forms include peeled and undeveined, tail-on (PUDT/PTO); peeled and deveined, tail-on (butterfly); and black tiger (BT) (no shell or legs should be left on the shrimp or in the package).

Shrimp are sold by count, which is expressed as a numerical range of shrimp per pound or kilogram. A count of 26–30 means there are between 26 and 30 shrimps per pound. The count often reflects a ‘peeled from’ number rather than the count per pound of shrimp in the package. A rule of thumb is that shrimp lose one size when peeled and another when cooked. Getting the correct count is critical since there can be substantial price differences among various sizes. Counts within a certain range should be as uniform in size as possible. Counts are sometimes expressed in names rather than numbers, such as ‘colossal: 10–15’, ‘jumbo: 21–25’ and ‘extra large: 26–30’.

Cooked shrimp comes in three main categories: cooked, peeled and deveined, tail-on (CP, tail-on); cooked, peeled and deveined, tail-off (CP, tail-off); or cooked in the shell.

4.2 PROCESSING (RAW)

For a typical plant layout, please see Appendix 3, Form #6, Plant Schematic and Tables 4.1a and 4.1b for the process flow of raw shrimp.

The harvested shrimp is delivered to the processing plant either live or dead on ice. Dead shrimp spoil rapidly unless kept on ice close to 32°F immediately after harvest. The shrimp is checked for quality (for details, see Chapters 6 and 7) immediately upon arrival at the processing plant. Next the product is checked for weight using a continuous weigh system (Sort-Rite International, Inc., Harlingen, TX 78551) (see Fig. 4.1).

Rules for handling on board

Cull from secondary products, storing each separately. Avoid trampling, or piling deeply on the deck. Protect from sun and drying effects of the wind by stowing

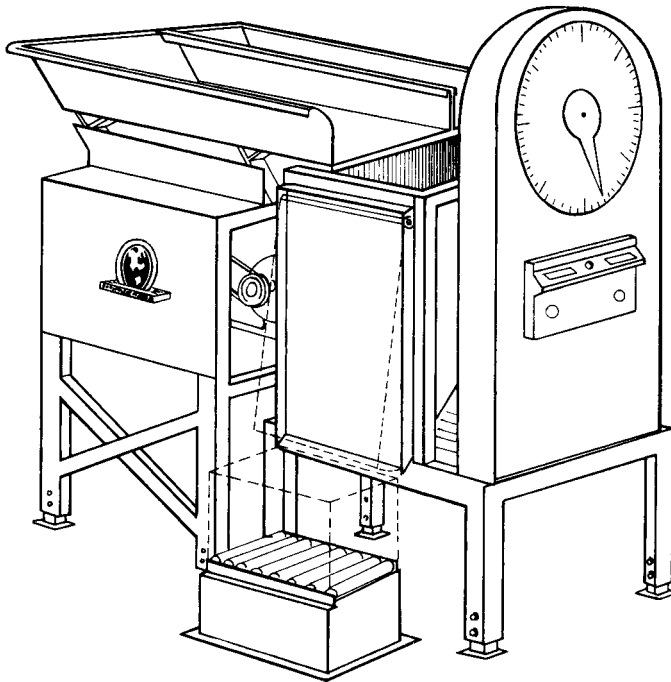
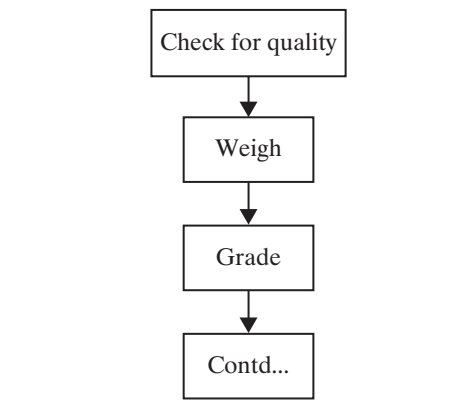
Table 4.1a Process flowchart for raw shrimp

Fig. 4.1 Weigh-rite continuous weigh system (Sort-Rite International, Inc., Harlingen, TX 78551).

properly in the hold. Wash thoroughly with clean seawater. Heading is desirable when practical. The shrimp should be dispersed throughout finely crushed ice, 1.5 times the weight of the shrimp. Draining runoff liquids must be unhampered. Sodium bisulfite treatments, if used, must be controlled in order to be effective and to limit the residual sulfite levels in the shrimp. The recommended method is to dip

the shrimp taken in a wire basket into a solution of 1.25% sodium bisulfite for about 1 min, then remove. The basket should be vigorously shaken while in the solution and after removal.

4.2.1 Grading (size and counts)

The raw tails flow to the grader, for example, a Sort-Rite Shrimp Grader (Sort-Rite International, Inc., Harlingen, TX 78551) (see Fig. 4.2) tank where the shrimp are dipped in an ice-bath followed by mechanical grading. Shrimp are graded in count per pound as explained above. Shell-on sizes range from under 10 to over 70. Over 70 counts are further divided into 71/90, 90/110, 110/130, 130/150, 150/200, 200/300, 250/350, 300/500 and 500 upwards. Peeled shrimp are sold according to their size before peeling (shell-on). On average, 25% of the green, HL shrimp is shell and legs, leaving with an average 75% weight of the green HL shrimp. For example, for the number of PD shrimp from a 21/25 green HL, divide 21 by 0.75 (= 28) and divide 25 by 0.75 (= 33). PD count from a 21/25 green headless should average about 28/33 per pound. It becomes important to know the PD count for the end-user, not only for cost control purposes but also in making decisions about

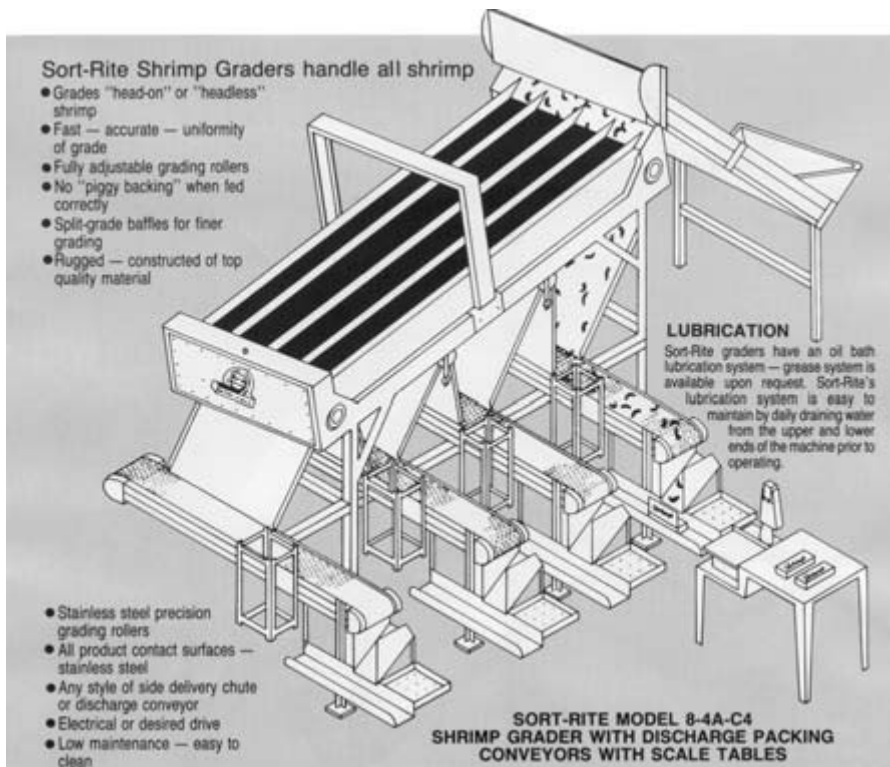


Fig. 4.2 Sort-Rite Shrimp Grader (Sort-Rite International, Inc., Harlingen, TX 78551).

further processing. From the grader, the tails are conveyed to the packing tables for further processing.

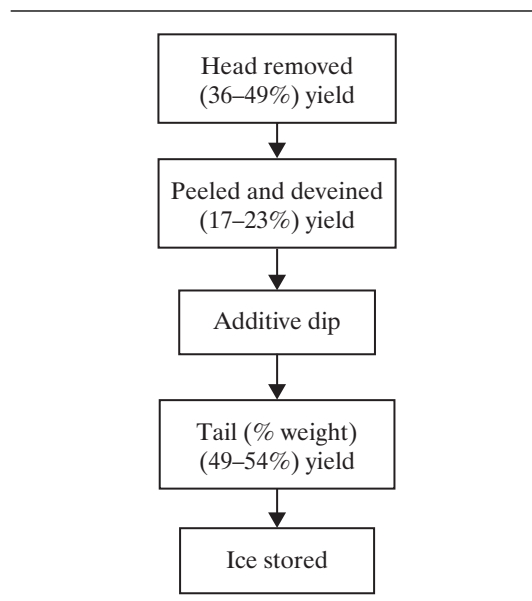
4.2.2 Beheading

The head (cephalothorax) of fresh shrimp contains organs rich in various digestive enzymes, which could lead to rapid deterioration of the flesh in the tail segment. The head is usually removed at the pond site if the processing plant is far away. In such a case, the shrimp go directly to the grader upon arrival. Otherwise, from the weigh system, the product moves to the beheading tables where the heads are separated from the tails either manually or mechanically. Manual beheading is done by squeezing the shrimp ahead of the tail section between the thumb and the fingers. Twisting the body at this juncture helps to remove the head. Most mechanical systems consist of a flat knife, which cuts off the head after correctly positioning the shrimp. Both guillotines and rotating knives are used. Beheading is still done manually in most of the developing countries, as labor is cheap and more efficient, resulting in higher yields when done by skilled workers.

4.2.3 Peeling and deveining

Peeling refers to removing shell from the meat. Shrimp is peeled and deveined by machines, although it is done manually in most of the developing countries. Typical peeling machines (for example, the automatic shrimp peeler, Laitram Machinery, Inc., P.O. Box 50699, New Orleans, LA 70150, see Fig. 4.3) singulate the HL shrimp and cut the shell along the body length on the dorsal side beside the vein. Once the

Table 4.1b Process flowchart for raw shrimp



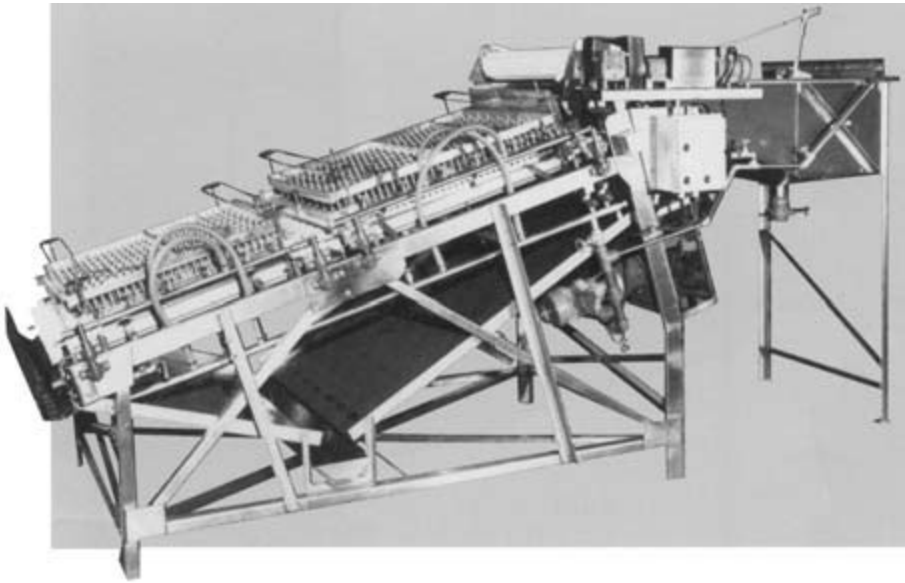


Fig. 4.3 Automatic shrimp peeler (Laitram Machinery, Inc., PO Box 50699, New Orleans, LA 70150).

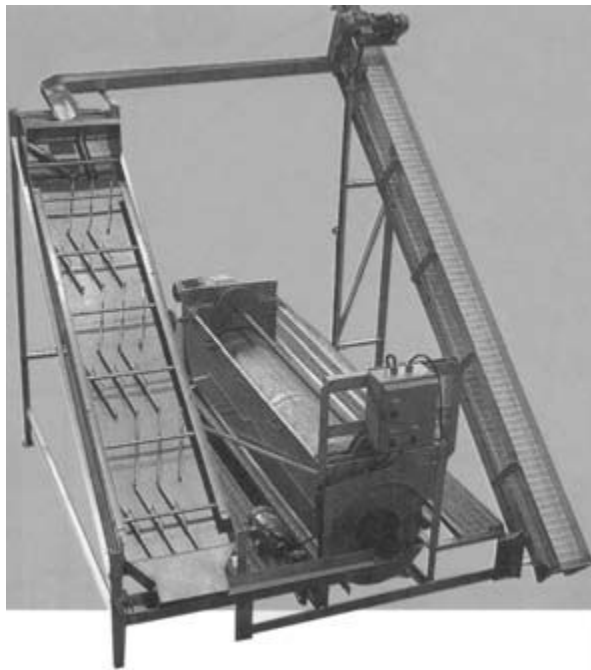


Fig. 4.4 Shrimp deveining machine (Laitram Machinery, Inc., PO Box 50699, New Orleans, LA 70150).

cut is made, the shrimp pass onto a bed of rollers. The rollers are closely spaced and rotate or oscillate such that adjoining rollers rotate in opposite directions. The shell is gripped by the rollers and stripped from the shrimp. The shrimp tail is too large in diameter to pass between the closely spaced rollers. Since the axes of the rollers slope downward, the shrimp move down and off the rollers in a continuous process.

The peeled shrimp then enter the deveining system (shrimp deveining machine, Laitram, Inc., see Fig. 4.4), which may be a separate machine or part of the peeler. The vein is the shrimp intestine that runs down the dorsal side near the surface. The vein is usually filled with food and sand; its removal improves product quality. Different systems are used, depending on the manufacturer, shrimp size and species. One system washes the vein out through a cut made along the vein by a knife. Another system removes the vein by catching it on indentations on the internal surface of a cylinder. The cylinder revolves in water, and as the shrimp pass through it, it removes the vein by catching it on the moving indentations on the drum.

Shrimp are further processed into a frozen (raw) or cooked and/or breaded product before being frozen and stored. Smaller sized shrimp are also dried and sold in the Far East. (See Tables 4.1c, 4.2, 4.3a and 4.3b flowcharts for processed shrimp.)

4.3 PROCESSING (COOKED)

Some manufacturers treat shrimp with sodium tripolyphosphate (STPP) before it is cooked. This is done to prevent drip loss of natural shrimp moisture and flavor and it protects against dehydration during frozen storage. Shrimp is cooked after peeling and deveining or first cooked in the shell and then peeled and deveined. The method and timing of cooking and uniformity of cook affect the final quality. Shrimp is steamed rapidly (to lock in the natural flavors) in special chambers (for example, the Laitram Model CTSB Split Hood—pure steam cooker, Laitram Machinery, Inc., New Orleans, LA 70150, see Fig. 4.5) where temperature and dwell time are electronically controlled. This model allows for physical separation of raw from cooked product to minimize airborne and other types of cross-contamination from the raw product to the cooked product. The product enters the cooking chamber on an open grid conveyor belt, which assures an even cook. In the cooking chamber, the product is exposed to steam wherein the product is cooked in a nonpressurized, saturated steam environment (100°C). The cooking time is controlled by the speed of the belt, which in turn is controlled by setting the time electronically. This control allows for adjustments of the cook time by the press of a button. The cooked product exits the cooker through the discharge module and is cooled rapidly. The yield of cooked meat could range from 22 to 35%.

4.4 DRIED SHRIMP

The cooked shrimp is either seasoned in a solution of common salt before drying or boiled in seasoned water (saltwater) and dried in forced air dryers, usually for 6–7 h. The dried shrimp are rotated in screen drums to remove shells and heads from the dried meat. Dried shrimp tails are put in polyethylene bags and stored in a cool and dry room. The yield of the dried meat ranges from 10 to 12% of the wet weight.

Table 4.1c Process flowchart for processing shrimp (continued)

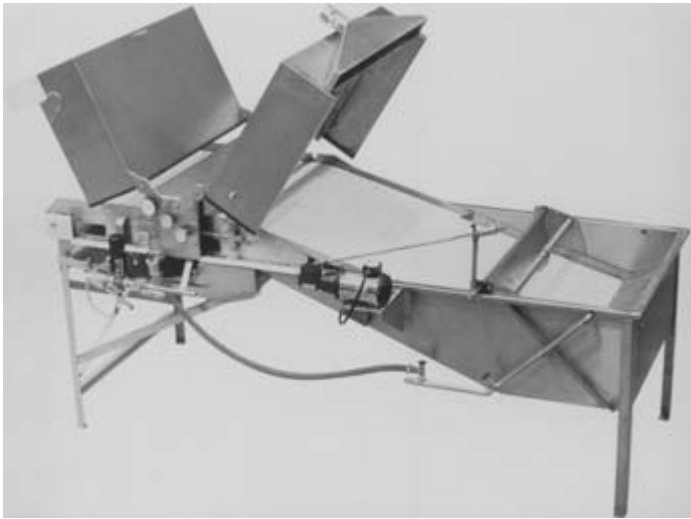
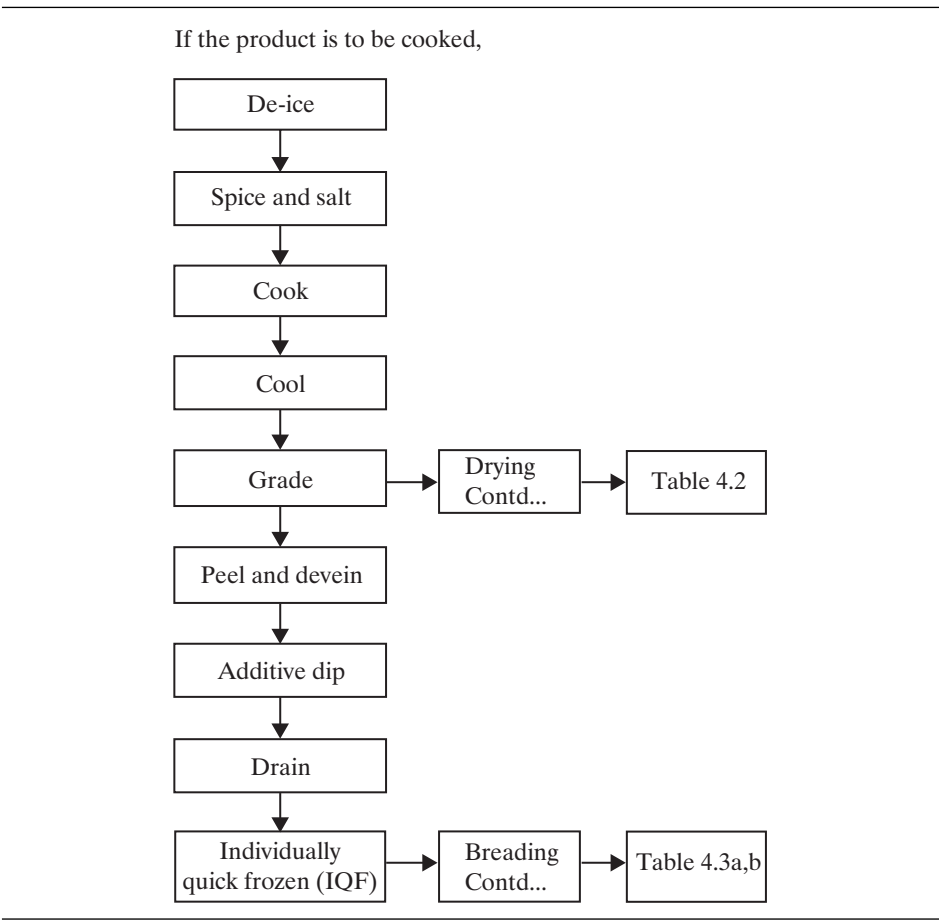
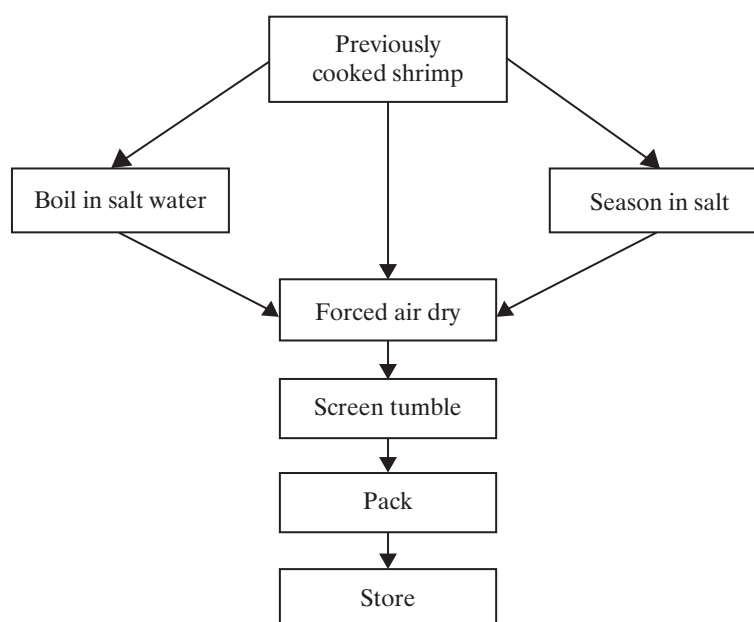


Fig. 4.5 Laitram Model CTSH Split Hood-pure steam cooker (Laitram Machinery, Inc., New Orleans, LA 70150).

Table 4.2 Process flowchart for processing dried shrimp

If the product is to be dried,



4.5 CANNING

Canned shrimp does not fall under HACCP rules but comes under a different set of regulations (thermally processed low-acid foods packaged in hermetically sealed containers – 21 CFR, Parts 108, 113 and 114). Therefore, HACCP is not shown for canned shrimp processing. The shrimp are prepared and cooked as described above, after which the product is packed in cans, packed in hot 2–3% brine solution, and a vacuum created either by passing steam into the can or by pulling vacuum before closing the can. The cans are then sterilized in a steam retort at temperatures of 105–115°C (220–240°F) and cooled. The exact time and temperature information for each product, size of the can, type of fill and any other variation has to be established by a processing authority. The time and temperature of cooking in the hermetically sealed can give a commercially sterile and shelf-stable product.

4.6 BREADING

Generally speaking, whites and most pinks (*Penaeus* spp.) are the preferred species because they are free from iodine flavor, and have a firm texture and good taste after cooking. Tiger shrimp and in general, non-*Penaeus* spp. are easy to overcook which results in a dry, stringy and abnormal texture.

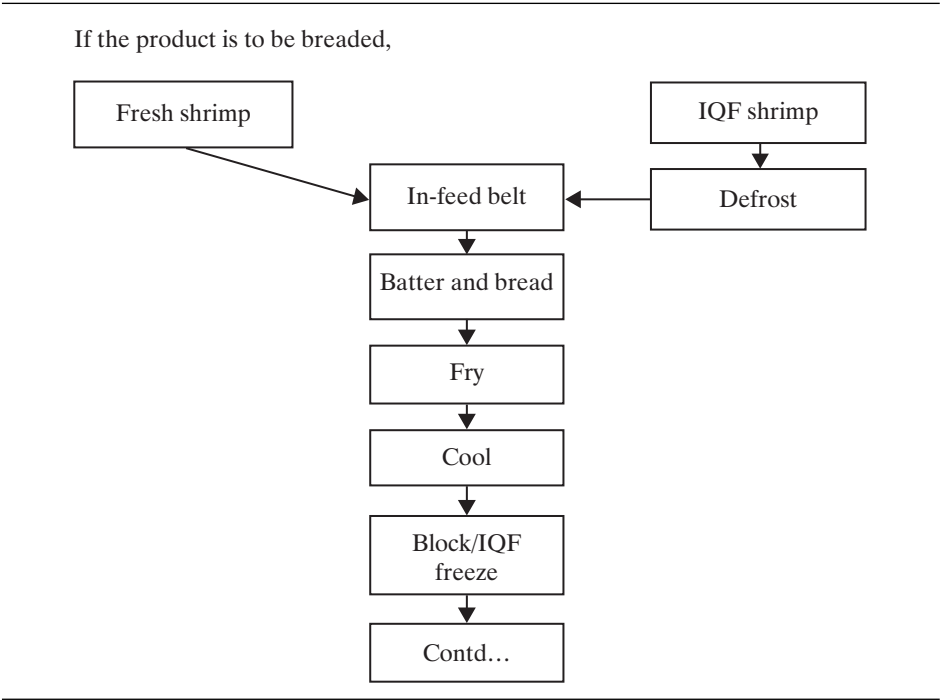
Breaded shrimp are usually made using raw headless white and most pink shrimp as the raw material. *Round* indicates that the shrimp has been cut down the back

only enough to take out the vein. *Butterfly* indicates that the cut down the back has gone almost completely through the shrimp, allowing the shrimp to be laid open, so that it is somewhat flat in appearance. A *western style* breaded shrimp indicates that the shrimp has been cut in half from the tail fin to the upper part of the shrimp, the two halves being held together by the tail. Another way to categorize is by the way in which the shrimp is breaded. Hand breaded indicates that the shrimp was held by the tail fin, dipped in batter and then breaded. Hand breading shrimp leaves the tail fin and the first half of the next section relatively free of breading. When fried the tail stands up at almost at a right angle, and makes for a very attractive plate appearance. Because it is the result of hand labor, the product tends to be very uniform in size. It is important to note that hand breaded does not mean lightly breaded.

Machine breading comes in two forms: clean tail and regular. The processing of clean tail machine breaded shrimp involves wiping of the excess breading from the tail fin only. The tails on these shrimp do not stand up in frying, but continue to lie flat. No effort is made to wipe the excess breading off the tail in processing regular machine breaded shrimp. If shrimp is labeled ‘lightly breaded’, it can have only 35% or less breading and 65% or more of shrimp in the product. If the label is ‘breaded shrimp’, the product cannot have more than 50% breading. Imitation breaded shrimp, legally could have less than 50% shrimp in the finished product.

Frying follows breading. Frying involves immersing the product in hot cooking oil for a predetermined time and temperature to cook partially or totally, and to allow binding of the batter and breading. Breaded products absorb oil and lose water

Table 4.3a Process flowchart for processing breaded shrimp



during frying with an overall gain in weight. Cooking times of 60–90 s are often used in which oil absorption is rapid during the first 30–40 s. Fryers used are both batch and continuous types. Continuous types are designed with a conveyor system passing through heated oil. A second hold-down conveyor is usually placed above the main conveyor to ensure that all products are completely immersed in the hot oil. Cooking time is adjusted by controlling the speed of the conveyor belt. The fryers usually have some type of oil filtration system and a pump to circulate the oil.

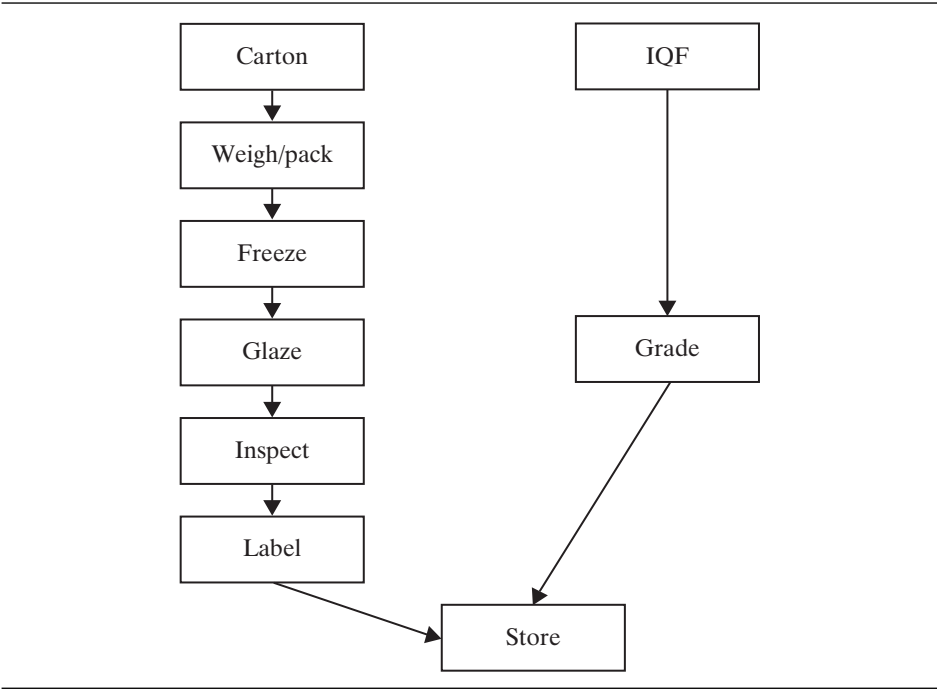
Batch systems consist of a heated container for the oil with a temperature controller. The product is placed in a wire mesh basket and immersed in the hot oil. After the desired cooking time, the basket is pulled out and drained, and the product is cooled. Some products require a cover to hold down the product in the basket. Batch-fryers are flexible and in a small plant they can be used for several products.

4.7 FREEZING

Traditionally, using cold air blasts (–40°F) blocks of shrimp are frozen in an insulated container (air-blast/spiral freezer), or in a contact plate freezer. Shrimp can also be individually quick frozen (IQF) by immersing or spraying them with liquid nitrogen/carbon dioxide (also called cryogenic freezing).

Cryogenic freezing systems utilize very large temperature differentials and are extremely effective but have high operating costs. Alternatively, (air) blast freezers

Table 4.3b Process flowchart for processing breaded shrimp (continued)



have low operating costs, but produce a significantly lower quality product and cause unnecessary weight loss.

A recent development in quick freeze technology utilizes mechanical freezing that nearly matches the performance of cryogenic systems. The Ross Boundary Layer Control (BLC; Ross Industries, Inc., Midland, VA 22728) system relies on a proprietary technology using maximized surface heat transfer coefficients at modest temperature differentials. Ross freezing tunnels utilize highly collimated air streams to attack the insulating boundary layer of air, which surrounds all objects and resists heat transfer. BLC technology accelerates freezing time by reducing the dwell time to as little as one-sixth of the time taken in conventional blast freezers, depending on the ratio of surface area to mass. For example, the dwell time for a 4 oz food product from a starting temperature of 32°F to 0°F is about 3.2 min compared to 17 min in a blast/spiral freezer. The additional advantages are reduced product dehydration (weight loss) and reduction in quality as compared to blast freezing.

The most common form is contact plate freezing, where food is held between hollow metal plates. Refrigerant is pumped through the hollow plates making the plate and the product in contact with it cold. Hydraulic pressure applied to the plates on each side of the product improves contact and increases the transfer of heat from the product to the plate.

The standard pack for green headless shrimp is a 5 lb or 2 kg (net weight) block. Gross weight of a 5 lb block with ice and packaging is usually between 6 and 7 lb. Blocks are packed in two styles: layer or finger and random or shovel. Layer packs are hand packed and arranged in waxed cardboard cartons covered with polyethylene film and placed in aluminum frames. The film is then folded over the contents to make an effective seal. The frames with boxes are then loaded into double contact plate freezers and frozen at -40°F. The recommended freezing rate is 0.25 inch/h. Shell-on shrimp are usually frozen in block form as described above.

Peeled and deveined shrimp are usually IQF either using a blast of cold air or cryogenically followed by glazing. Most IQF products are packed from 1 to 30 lb in polyethylene bags.

4.7.1 Glazing

After the product is frozen, it is taken out of the freezer and sprayed with ice-cold water. If plate frozen, the top flap of the package is opened and a 32°F (0°C) water spray (for example, the Sort-Rite glazing machine) is applied. The package is then closed and put upside down into the master carton. Any excess moisture still within the package will go to the top of the box and act as a further sealant. Glaze is usually provided to prevent dehydration (freezer burn) and oxidation of the product while in cold storage by supplementing the protective effect of the outer package.

Sometimes thickening agents such as carboxy-methyl cellulose (CMC), sodium alginate, and antioxidants such as ascorbic acid and preservatives are used in the glaze solution to extend the shelf life. Such additives provide structure control, minimize weight losses, seal the flavor and act as a barrier against oxygen and moisture.

4.8 COLD STORAGE

Once the freezing and glazing is complete the product goes into cold storage until it is distributed. A standard cold storage facility is designed to hold a month's production.

4.9 ICE PRODUCTION AND STORAGE

The most important raw material in shrimp processing is ice. The shrimp should be immediately iced after harvesting from the pond or from the ocean. Typical usage is 1–1.5 lb of ice per 1 lb of shrimp. Ice storage should have three days' capacity so that there is always sufficient ice for the product being processed.

4.10 HACCP IN SHRIMP PROCESSING

Processing of raw penaeid shrimp is chosen here to illustrate the development of a HACCP plan following the basic principles described in Chapter 2. The first four steps remain the same if the shrimp culture and processing is conducted as an integral operation in a single location:

- (1) assemble a HACCP team and assign the responsibilities;
- (2) develop an organization chart and narrative;
- (3) describe the end product and its intended use and distribution;
- (4) identify and list product ingredients and raw material;
- (5) develop an operational flowchart for each type of processing (raw, cooked, dried, breaded and frozen are shown under sections 4.2–4.7); and
- (6) develop a plant schematic showing product flow and employee traffic patterns within the plant for that specific product (for details, see Chapter 3, sections 3.1.1–3.1.6).

4.10.1 General guidelines in developing a HACCP plan

Next, develop the hazard analysis (HA) worksheet through steps 7–13 (HACCP principles) as described in section 3.2. The following example (see Tables 4.4–4.7) illustrates hazard analysis, critical control points, control measures, critical limits, monitoring, corrective actions, and record keeping requirements in processing raw, cooked, breaded and dried shrimp. The analysis shown here is neither complete nor pertinent to any specific situation. The actual hazards are specific to the product, process and location and must be analyzed by the designated HACCP team of the company before a HACCP plan is developed.

Table 4.4 Hazard analysis for raw shrimp

Processing step	1. Unloading/purchasing/receiving/examination Critical: Yes/No*	2. Thaw Critical: Yes/No*	3. Examination Critical: Yes/No*
Control point	Receiving area: dock, containers, tanks	Thaw tank	Belt or table
Hazards	1. Mislabeling (misrepresentation) 2. Decomposition 3. Excessive additive (bisulfite) 4. Pathogen growth 5. Contaminates: foreign material, fuel oil	1. Contamination from pathogenic microorganisms, unsanitary equipment and/or nonpotable water 2. Temperature abuse 3. Foreign material	1. Microbial contamination 2. Temperature abuse leading to growth of pathogenic microorganisms
Critical limits	1. Species consistent with purchase specifications 2. Two subsamples not consistent with acceptable spoilage characteristics of the product 3. Any shell-on product which possesses rough, 'sandpaper' shell texture 4. Product temperature not to exceed 40°F 5. No detectable levels of contamination that render the product unwholesome or unsafe	1. Thaw tank and/or thaw racks must be cleaned and sanitized prior to use 2. Temperatures must be maintained at <45°F 3. Only potable water will be used for thawing 4. Frozen product will not be placed in tanks until all foreign material has been removed from tank and immediate vicinity	1. No product must come in contact with inadequately cleaned or sanitized work surfaces, containers, utensils or equipment 2. No product will be exposed to nonrefrigerated temperatures for periods in excess of 30 min
Preventive measures	1. Written purchase specifications 2. Train personnel to identify acceptable organoleptic characteristics 3. Train personnel to identify acceptable shell texture 4. Control time and temperature on dock, and train personnel to check product temperatures	1. Thoroughly clean and sanitize equipment on a routine basis 2. Control temperatures, and train personnel to check temperatures 3. Use potable water 4. Train personnel to clean debris from area prior to use	1. Thoroughly clean and sanitize equipment on a routine basis 2. Train personnel in proper hygiene and GMPs 3. Maintain adequate process flow to minimize product exposure to ambient temperatures

5. Train personnel to identify contamination and foreign materials 6. Equipment sanitation	1. Visual examination 2. Organoleptic exam (visual and odor) of five $\times$ 1 lb subsamples per 100 lb of incoming product 3. Examine shell texture of five $\times$ 1 lb subsamples per 100 lb of incoming product 4. Check product temperature at a minimum of two locations of the incoming lot 5. Visual and organoleptic (odor) examination	1. Visual observation and check of sanitation log 2. During the thaw cycle temperature will be checked every 2 h	1. Visual observations and check of sanitation log, temperature logs, etc.
Monitoring procedures			
Corrective actions	1. Reject product or correctly relabel 2. Hold product if two subsamples are not consistent with organoleptic characteristics of species. Product to be further tested according to FDA compliance guidelines. If not in compliance, product will be rejected 3. Reject product if any subsample possesses a sandpaper texture, or may hold product for subsequent laboratory confirmation of bisulfite residuals. If lab test confirms levels > 100 PPM, reject shipment	1. If tanks and equipment have not been adequately cleaned and sanitized, cleaning and sanitizing are complete 2. If temperature exceeds 45°F, ice will be added to bring temperature to $< 35^\circ\text{F}$	1. If belt and/or table have not been adequately cleaned and sanitized, hold product until cleaning and sanitizing are complete 2. Remove product from the belt conveyors/tables when product movement is disrupted for periods in excess of 30 minutes. Thoroughly ice the product until product flow is restored

continued

Table 4.4 continued

Processing step	1. Unloading/purchasing/receiving/examination Critical: Yes/No*	2. Thaw Critical: Yes/No*	3. Examination Critical: Yes/No*
	4. If any one of the two temperature readings is > 40°F; hold shipment for decomposition analysis. If analysis exceeds FDA compliance guidelines, reject shipment 5. The nature of the contaminate will warrant different actions: detectable levels of fuel oil will result in rejection; other contaminants may be removed by washing or by hand		
Records	1. Purchase specifications 2. Receiving and laboratory logs 3. Temperature logs	1. Sanitation logs 2. Temperature logs, etc.	1. Sanitation logs 2. Temperature logs, etc.
Verification	1. Checking the receiving records against purchase specifications for every shipment 2. Temperature logs	1. Checking sanitation logs daily (by supervisor)	1. Checking all records such as sanitation logs daily (by supervisor)

Table 4.4 continued

Processing step	4. Grading for size and counts Critical: Yes/No*	5. Beheading Critical: Yes/No*	6. Peeling/deveining Critical: Yes/No*
Control point	Size grader	Beheading station	Machine/shrimp holding trough/ peeling table/in-feed belt
Hazards	1. Economic fraud (incorrect sizing) 2. Microbial contamination	1. Time-temperature abuse 2. Microbial contamination from machine/human	1. Microbial contamination from machine or human 2. Time-temperature abuse potential 3. Foreign objects
Critical limits	1. Any package containing more shrimp (by count) per pound than label declaration indicates 2. Machine must be cleaned and sanitized prior to use	1. Machine must be cleaned and sanitized prior to use 2. Personnel should wash and sanitize themselves before handling the product	1. Proper sanitation control procedures
Preventive measures	1. Equipment calibration 2. Regular cleaning, sanitizing and maintenance of equipment 3. Employee training in equipment maintenance, cleaning and sanitizing	1. Equipment calibration 2. Regular cleaning, sanitizing and maintenance of equipment 3. Employee training in equipment maintenance, cleaning and sanitizing	1. Frequent cleaning and sanitizing of equipment. SSOPs are designed to prevent contamination, time-temperature abuse and foreign objects

continued

Table 4.4 continued

Processing step	4. Grading for size and counts Critical: Yes/No*	5. Beheading Critical: Yes/No*	6. Peeling/deveining Critical: Yes/No*
Monitoring procedures	1. Check counts at least twice per hour 2. Visual observation and check of sanitation log	1. Check product visually at least twice per hour 2. Visual observation and check of sanitation log	1. Visual observation 2. Check sanitation log
Corrective actions	1. Calibrate machine, and regrade product produced from the last calibration check 2. If machine has not been adequately cleaned and sanitized, hold product until these procedures are completed	1. Calibrate the machine, separate product that is visually imperfect and reprocess manually 2. If machine has not been adequately cleaned and sanitized, hold product until these procedures are completed	1. If tanks and equipment have not been adequately cleaned and sanitized, product will be held until cleaning and sanitizing are complete 2. If temperature exceeds 45°F, ice will be added to bring temperature to <35°F
Records	1. Process log for counts and machine calibration 2. Equipment maintenance log 3. Sanitation logs	1. Sanitation log 2. Calibration log	1. Sanitation log 2. Temperature log
Verification	1. Daily supervisor check of operator logs and sanitation logs 2. Weekly check of equipment maintenance logs	1. Check sanitation and calibration logs daily	1. Check sanitation and temperature logs daily

continued

Table 4.4 continued

Processing step	7. Additive treatments Critical: Yes/No *	8. Packing/weighting Critical: Yes/No *
Control point	Dip tank/mixer/vacuum tumbler	Packing/weighting table
Hazards	1. Unapproved/non-GRAS (Generally Recognized as Safe) additive 2. Excessive levels 3. Contaminated with microbes and filth 4. Containers with unlabeled food additives	1. Incorrect label 2. Error in filling or weighing 3. Foreign material 4. Microbial contamination
Critical limits	1. Only additives on GRAS list can be used 2. Use of approved additives will be in compliance with current regulatory policies (CGMPs) 3. Dip solutions must be made from potable water, and new solutions formulated every 2 h 4. Follow supplier directions for their use	1. All product packages must be correctly labeled 2. Net weight (not to include glaze) of all products must not be less than declared 3. No detectable levels of contamination (foreign materials or microbial) that would render the product unsafe or unwholesome
Preventive measures	1. Written specifications indicating additives approved for use 2. Written specifications indicating formulation of additives dips and its application 3. Train personnel in additive formulation and application	1. Calibration of scales 2. Include product code on package 3. Purchase specifications for packaging materials 4. Employee training in areas of personal hygiene, sanitation, and package inspection

continued

Table 4.4 continued

Processing step	7. Additive treatments Critical: Yes/No*	8. Packing/weighing Critical: Yes/No*
Monitoring procedures	- Supervisory checks of additives used and application - Additives use log indicating date and time of formulation	- Daily checks of scales - At a minimum of once per hour, a package will be pulled by a supervisor to check for weight and label compliance
Corrective actions	- If unapproved additives are used, product will be held and regulatory authorities contacted as to disposition of product - If there is any indication of improper additive formulation or application, product will be held until appropriate analysis can be completed to determine if additive residual is within compliance guidelines. If results indicate that residuals are not in compliance, regulatory authorities will be contacted as to disposition of product - Additive tips used in excess of 2 h will be discarded and a new solution formulated	- Calibrate scales as appropriate - Product and packages found not to be in compliance with label declarations must be held and reworked - Product found to be contaminated such that it is unsafe or unwholesome will be rejected
Records	Log of additives usage and purchase including date of opening and expiry of each container	- Process records for equipment calibration - Process control charts for weighing equipment
Verification	Daily supervisor checks of operator logs	- Check records daily - Calibrate the scales weekly

* Determined by using the CCP decision tree, see Form #8, Appendix 3.

Table 4.5 Hazard analysis for cooked shrimp*

Processing step	1. Cooking Critical: Yes*/No	2. Cooling Critical: Yes/No*
Control point	Cooker	Cooling equipment
Hazards	1. Inadequate cooking leading to pathogen growth 2. Unsanitary cooker 3. Inadequate water/steam quality 4. Post processing contamination	1. Inadequate cooling rate (pathogen growth and toxin formation) 2. Microbial contamination 3. Water and ice quality 4. Cross-contamination
Critical limits	1. Product will not be cooked for less than the established time and temperature criteria. For example, 2.5 min minimum time at temperatures not less than 210°F 2. Cooker (racks, trays, trolleys) must be cleaned and sanitized prior to use 3. Only potable water will be used for cooking (boiling/steaming) 4. No cross-contamination of cooked product with: raw product, utensils used for handling raw product, or employees with raw product responsibilities	1. Cooked product must be cooled to <40°F within 2 h of cooking 2. Cooling equipment (belts, racks, etc.) must be cleaned and sanitized prior to use 3. Only potable water will be used for cooling (ice, brine, sprays) 4. No cross-contamination of cooked product with: raw product, utensils used for handling raw product, or employees with raw product responsibilities
Preventive measures	1. Establish written specifications for time and temperature of cook 2. Train employees responsible for cooking in proper cooking procedures and handling of cooked product 3. Establish written specifications for proper water treatment and boiler maintenance 4. Train employees in proper cleaning and sanitizing	1. Establish written specifications for cooling procedures 2. Train employees in proper cleaning and sanitizing 3. Train employees in proper handling of cooked product
Monitoring procedures	1. Monitor cook times and temperatures 2. Visual observations and checks of sanitation log 3. Monitor water treatment and boiler maintenance	1. Monitor cooling temperatures and times 2. Visual observations and checks of sanitation log 3. Monitor water treatment and boiler maintenance 4. Supervisory checks of product handling

continued

Table 4.5 continued

Processing step	1. Cooking Critical: Yes*/No	2. Cooling Critical: Yes/No*
Corrective actions	1. Product receiving an insufficient cook will be separated and held in refrigeration (not to exceed 48h) until properly evaluated for further disposition (for example, recooked). Cooking of reworked product will be held in the cooker until entire cook cycle completed 2. Cooked product cross-contaminated with raw product, raw product utensils, or employees handling raw product will be either destroyed or held in refrigeration (not to exceed 48 h) until recooked. Cooking of reworked product will begin at time zero and the entire cook cycle completed 3. Products cooked in water or steam, treated with non-approved compounds, will be held under refrigeration and the regulatory authorities contacted for determination of appropriate disposition	1. Product with temperatures >40°F after 2 h will be immersed in slush ice to promote rapid cooling 2. If cooling equipment is not adequately cleaned and sanitized, product will be held until cleaning and sanitizing is complete 3. Cooked product cross-contaminated with raw product, raw product utensils, or employees handling raw product will be either destroyed or held in refrigeration (not to exceed 48h) until recooked. Cooking of reworked product will begin at time zero and the entire cook cycle completed
Records	1. Process logs: cooking records/data logger 2. Sanitation logs	1. Process logs 2. Sanitation logs
Verification	1. Check records daily 2. Weekly review of monitoring, verification and corrective action records 3. Calibrate temperature-recording devices against mercury in glass thermometer weekly 4. Calibrate the mercury in glass thermometer yearly	1. Check records at the end of every shift 2. Calibrate thermometer weekly

* Determined by using the CCP decision tree, see Form #8, Appendix 3.

Table 4.6 Hazard analysis for breaded shrimp

Processing step	1. Battering and breading Critical: Yes/No*
Control point	Battering and breading station
Hazards	1. Microbial contamination 2. <i>Staphylococcus aureus</i> growth and toxin formation 3. Foreign material
Critical limits	1. Total plate counts should not exceed 100 000/g sample 2. Batter temperature not to exceed 50°F for more than 12 h 3. The product should be free from foreign material
Preventive measures	1. Batter temperature control 2. Washing tanks as per the schedule 3. Changing batter on a regular schedule 4. Use of potable water 5. Personal hygiene
Monitoring procedures	1. Monitor batter temperature 2. Frequency of batter change 3. Test for total plate counts
Corrective actions	1. Adjust the batter refrigeration controls if the temperature goes over 50°F within 5 h. Destroy batter and any product produced during the deviant period 2. If the total plate counts exceed the critical limits, equipment shall be emptied and thoroughly cleaned and sanitized
Records	1. Quality control log: recorder thermometer chart
Verification	1. Check records daily 2. Calibrate thermometer weekly 3. Review monitoring, corrective action and verification records weekly

* Determined by using the CCP decision tree, see Form #8, Appendix 3.

Table 4.7 Hazard analysis for dried shrimp

Processing step	1. Drying Critical: Yes/No*
Control point	Dryer
Hazards	1. Pathogenic microbial growth 2. Unsanitary dryer
Critical limits	1. Minimum drying time (for example, 6 h at a minimum oven temperature of 140°F) 2. Reduce water activity to 0.85 or less within 8 h 3. Dryer (racks, trays, trolleys) must be cleaned and sanitized prior to use
Preventive measures	1. Establish written specifications for time and temperature of drying from the processing authority 2. Train employees in proper cleaning and sanitizing
Monitoring procedures	1. Monitor drying time/temperatures and water activity 2. Visual observations and checks of sanitation log
Corrective actions	1. If the time/temperature requirement is not achieved, extend the drying process 2. If 0.85 water activity is not achieved within 8 h, continue drying cycle, hold the product and have it evaluated by a competent authority 3. Products treated with non-approved compounds will be held under refrigeration and the regulatory authorities contacted for a determination of appropriate disposition
Records	1. Processing log 2. Time/temperature data logger
Verification	1. Document scheduled process approved by a competent authority 2. Daily record review 3. Weekly review of monitoring, verification and corrective action records 4. Calibration of water activity meter

* Determined by using the CCP decision tree, see Form #8, Appendix 3.

5 General Concepts of Sampling and Monitoring

5.1 INTRODUCTION

Monitoring means measuring a characteristic of a product or a process to determine compliance with a critical limit. Monitoring can be by either observation or measurement. The choice between the two is dependent on the critical limit, available methods to monitor, realistic time delays and costs. Observation is usually qualitative. For seafood, monitoring includes sensory and visual checks, pre-operational checks of sanitary conditions, etc. Monitoring may also involve observing whether preventive measures at a critical control point (CCP) are being performed; for example, the checking of an exporter's health certificate by a shrimp processor who depends on imported shrimp for raw material. The collector must compare the observation to the critical limit, leaving room for interpretation. The collector also records the observation, usually on a checklist.

Measurement is always quantitative and it can be biological, chemical or physical in nature. Examples of monitoring through measurement include testing for filth (physical), indole content to determine the extent of decomposition (chemical) or the presence of *Salmonella* (microbiological) in shrimp.

The monitoring activity may be continuous or noncontinuous. A monitoring instrument is one that produces a continuous record of a measured value. For example, the time and temperature of shrimp while it is being cooked can be monitored and recorded on a temperature-recording chart. The frequency of noncontinuous monitoring is dependent on various factors such as normal process variations, proximity of normal values to the critical limit, cost of the product and the economic loss if the critical limit is violated. Examples of noncontinuous monitoring include testing for decomposition, or net weight content of shrimp.

If the monitoring is not continuous (on every unit), then a sampling plan must be in place to identify when and how much is monitored. In addition, measurement requires calibrated equipment. The collector records the measurement on a data sheet. As processing systems become more sophisticated, fully automated (computerized) measurement systems are often incorporated.

Monitoring is performed at CCPs at a location that accurately reflects the state of the critical limit. The selection of the data collector is critical. This person must have easy access to the CCP plus the skills and knowledge to understand the collection activity and its importance. Sometimes, the collector must be trained or provided with special tools (calibrated equipment, etc.) to perform the job. Most importantly, the data collector must be unbiased. In order to identify when and how much to monitor in an unbiased fashion, one needs to understand the theory of 'sampling'.

5.2 BASICS OF SAMPLING

Sampling is the process of evaluating a portion of a product for the purpose of accepting or rejecting an entire lot as either conforming or not conforming to a quality specification. The main advantage of sampling is economy. Although there are some added costs involved in designing and administering a sampling plan, there are lower overall costs associated with inspecting only part of a lot.

5.2.1 Major disadvantages of sampling

- (1) Increased risks of passing defective lots.
- (2) Administrative costs.
- (3) Less information than gained from 100% inspection.

5.2.2 When is sampling used?

- (1) When the cost of inspection is high in relation to the cost resulting from passing a defective lot.
- (2) When 100% inspection is monotonous, causing inspection errors.
- (3) When the inspection is destructive.
- (4) When the monitoring is not continuous (on every unit), then a sampling plan must be in place to identify when and how much is monitored.

5.2.3 When is sampling most effective?

- (1) When it is preceded by a prevention program such as HACCP that achieves an acceptable level of conformance quality.
- (2) When statistics are used, without which sampling costs can be high without providing any useful information.

5.3 DEFINITIONS OF BASIC SAMPLING TERMS

- (1) *Lot size (N)*: A collection of units of similar product from which a sample is drawn and inspected.
- (2) *Sample size (n)*: One or more units selected at random from a lot without regard for their quality.
- (3) *Lot percent defective*: This percent is found by dividing the number of defectives by the lot size and then multiplying by 100 ($D/N \times 100$, where D = number of defectives and N = lot size).
- (4) *Sample percent defective*: This percent is found by dividing the number of defectives by the sample size and then multiplying by 100 ($D/n \times 100$, where D = number of defectives and n = sample size).
- (5) *Accept number (Ac or c)*: This is the number of defectives that (if found in a random sample) allows acceptance of the balance of the lot.
- (6) *Reject number (Re)*: This is the number of defectives that (if found in a random sample) dictates rejection of the entire lot and returning it for screening (or 100% inspection).

- (7) *Defect*: A characteristic of a part that does not conform to specifications.
- (8) *Critical defect*: This classification of defect is one that experience or judgment indicates is likely to cause unsafe conditions for the consumer; or a defect likely to prevent performance of the function of the major end-item.
- (9) *Major defect*: This is a defect other than critical that may cause the product to fail, cause poor performance or shortened life, or prevent interchangeability.
- (10) *Minor defect*: A defect that is not likely to reduce materially the usability of the unit.
- (11) *Producer's risk (alpha risk)*: The probability of rejecting a good lot.
- (12) *Consumer's risk (beta risk)*: The probability of accepting a bad lot.
- (13) *Attribute*: An item that is either good or bad.
- (14) *Variable*: Not only is an item determined to be good or bad but also how good or how bad.
- (15) *Confidence level*: This is 1 minus the applicable risk. In sampling, it is the degree of uncertainty that a sample can be said to be representative of the true population.
- (16) *Acceptable Quality Level (AQL)*: This is the maximum percent defective that is considered satisfactory as a process average by the producer and the consumer. In other words, this is the worst quality level that is still considered satisfactory. In some instances, it is known as the consumer's risk and has been standardized at 0.1.
- (17) *Rejectable Quality Level (RQL)*: This is definition of unsatisfactory quality. The probability of accepting a RQL lot should be low.
- (18) *Indifference Quality Level (IQL)*: This is a quality level somewhere between the AQL and RQL. It is frequently defined as the quality level having a probability of acceptance of 0.5 for a given sampling plan.
- (19) *Attribute plans*: A random sample is taken from the lot and each unit classified as acceptable or defective. The number of defectives is then compared with the allowable number stated in the plan and a decision is made to accept or reject the lot.

5.4 TYPES OF SAMPLING PLANS

Sampling plans are of two types: attribute plans and variable plans (Kanduri and Hudak-Roos, 1993a, b). Sampling plans are used to determine whether or not the product produced (usually on a lot-by-lot basis) satisfies one or more specifications. The results obtained from sampling are then used to judge the quality condition of the total product (lot) under evaluation. Based on this inferential process, there always exists the possibility of making an incorrect decision on the actual lot status, i.e. rejection of a conforming lot or acceptance of a nonconforming lot. In particular, an inadequate awareness of the inherent limitations of a sampling plan may lead to an unjustified sense of security by those responsible for its use.

When encountering lots that vary in quality, the possibility that a sampling plan will lead to an incorrect decision on the actual lot status is usually described by that plan's operating characteristic (OC) curve. This curve indicates the chance of lot acceptance for lots having varying quality and can be presented in tabular and graphical form.

5.4.1 Attribute plans

These can be two-class, three-class and above, depending upon the complexity of the situation. The sampling plan for attribute sampling consists of three numbers.

Example

Sample size $n = 80$

The accept number $Ac = 4$

The reject number $Re = 5$

Two-class sampling plan

For the simplest type of sampling plan, a two-class attribute plan (i.e. each sample unit selected is judged to be nonconforming or conforming relative to a certain specification, or the number of defects per sample unit is counted), a few selected values on the OC curve can be used to describe the performance of that plan. These so-called reference values are the AQL (*Acceptable Quality Level*, i.e. the actual percent of nonconforming sample units in the entire lot for which the sampling plan will indicate lot acceptance 95% of the time), the IQL (*Indifference Quality Level*, i.e. the actual percent of nonconforming sample units in the entire lot for which the sampling plan will indicate lot acceptance 50% of the time) and the RQL (*Rejectable Quality Level*, i.e. the actual percent of nonconforming sample units in the entire lot for which the sampling plan will indicate lot acceptance 10% of the time). In the following two-class sampling plan, the reference values (AQL, RQL and IQL) are explained.

A 10 000 lb lot containing 2000 5-lb cartons of a certain product is to be evaluated for one or more specifications based on the two-class plan $n = 6$, $c = 1$, where n denotes the sample size and c the acceptance number. That is, when six (n) cartons selected at random from the entire lot have one (c) or fewer nonconforming cartons, the lot is accepted, whereas when two or more of the six cartons are nonconforming, the lot is rejected. This sampling plan has the following performance characteristics:

$$AQL = 6.3\% \quad IQL = 26\% \quad RQL = 51\%$$

Interpreting AQL, IQL and RQL for a certain specification:

AQL: If the above 10 000 lb lot (2000 5-lb cartons) actually has 6.3% (126) nonconforming cartons, this sampling plan will indicate lot acceptance 95% of the time (or lot rejection 5% of the time). Note: Implicit in the selection of a sampling plan is that the plan's AQL represents for the producer/consumer, seller/buyer, etc., an agreed upon percent nonconformance, for which the sampling plan will accept the lot most of the time (usually taken as 95% of the time).

IQL: If the lot (2000 5-lb cartons) actually has 26% (520) nonconforming cartons, then this sampling plan will indicate lot acceptance 50% of the time (or lot rejection 50% of the time).

RQL: If the lot (2000 5-lb cartons) actually has 51% (1020) nonconforming cartons, then this sampling plan will indicate lot acceptance 10% of the time (or lot rejection 90% of the time). Note: Implicit in the selection of a sampling plan is that the plan's RQL represents for the producer/consumer, seller/buyer, etc., an agreed upon percent defective for which the lot will be rejected most of the time (usually taken as 90% of the time).

Table 5.1 Effect of changing acceptance number from 1 to 0

Sampling plan	AQL (%)	IQL (%)	ROL (%)
n = 6, c = 1	6.3	26	51
n = 6, c = 0	0.85	11	32

What if the above sampling plan is considered too 'loose', i.e. too many nonconforming products may be accepted? To make the plan 'tighter', i.e. less nonconforming product accepted, usually the first reaction is to increase the sample size (n). However, another way is to keep the sample size the same but reduce the acceptance number (c). For example, rather than using the sampling plan n = 6, c = 1, suppose n = 6, c = 0 were considered, i.e. accept the lot if none of the six sample units (cartons) are nonconforming, whereas reject the lot if one or more are nonconforming. What effect would changing the acceptance number (c) from one to zero while keeping the sample size (six) the same have on the performance characteristics? This information is given in Table 5.1.

This alternative plan (n = 6, c = 0) is certainly more favorable to the consumer/buyer in that less nonconforming product will be accepted; however, the relatively small AQL may be too restrictive on the producer/seller.

Three-class sampling plan

Not all sampling plans are of the simple two-class type. Frequently in practice, three (or more) class plans are used. This is particularly the case when food lots are examined microbiologically for compliance with a microbiological standard, tolerance or guideline. In three-class plans, the concepts of lowercase ('little') m and upper case ('big') M are employed. Lower case m usually represents the numeric limit of a target microorganism present in a product manufactured under Good Manufacturing Practices (GMPs). On the other hand, upper case M represents the numeric limit of the same target microorganism that is considered to be unacceptable; therefore, the entire lot should be rejected should any sample unit exceed M. For example, consider the following three-class plan for *Staphylococcus aureus*: when no sample unit of five analyzed exceeds 1000/g and no more than one of the five sample units exceeds 500/g but not 1000/g, the lot is in compliance. In this context, 500/g is m and 1000/g is M. This three-class plan is conventionally represented as follows: n = 5, c = 1, m = 500/g, M = 1000/g.

For three or more class sampling plans, a simple description of their performance characteristics using one set of values for the AQL, IQL and RQL is not feasible. These values would have to be reported for one classification at various fixed levels of other classifications and this soon becomes somewhat complicated and of questionable practical use. Generally, the most useful presentation of the performance characteristics for three or more class plans is to employ two or more way tables.

For example, the performance characteristics for the three-class plans given above, i.e. n = 5, c = 1, m = 500/g, M = 1000/g, can be presented as follows:

Let P = the actual percent of all possible sample units in the lot exceeding 500/g but not 1000/g.

Q = the actual percent of all possible sample units in the lot exceeding 1000/g.

Table 5.2 Probability (percent) of lot acceptance

P	Q				
	0	10	20	30	40
0	100	59	33	17	8
10	92	53	29	14	6
20	74	41*	21	9	4
30	53	27	12	5	1
40	34	16	6	2	< 1

* Example interpretation: Suppose a lot consists of 40 000 lb of product. When this lot contains P = 20% (8000 lb) exceeding 500/g but not exceeding 1000/g and Q = 10% (4000 lb) exceeding 1000/g, this three-class plan will indicate lot acceptance 41% of the time. The other results in the table can be interpreted in like manner.

Table 5.3 Lot size v. probability of lot acceptance

N	Pa (%)
100	84.90
1000	84.48
10 000	84.44
100 000	84.44

Then the probabilities (percent) of lot acceptance, for selected values of P and Q, are given in the two-way table (Table 5.2).

5.5 TEN PERCENT RULE

A frequently asked question is: what effect does lot size have on the performance characteristics of sampling plans? The answer may be surprising and perhaps, to the nonsampling lay person, unbelievable. When the sample size (n) is less than 10% of the lot size (N), then the probability of lot acceptance is negligibly affected by lot size. For example, suppose a lot contains 12% nonconforming sample units and the single sampling plan n = 6, c = 1 is to be used. The probability of lot acceptance (Pa) for different values of lot size (N) is given in Table 5.3.

5.6 RESAMPLING

Another sampling consideration is the sometimes-used practice of resampling, i.e. when the first sample indicated lot rejection, pull another sample and take action on the lot based only on the results of the second sample. Note that resampling is not to be confused with so-called double sampling plans in which lot acceptance, rejection or taking an additional sample are options based on the structure of the double sampling plan. The net effect of resampling is to increase the chance of accepting nonconforming product. For example, suppose the single sampling plan n = 5,

$c = 0$ is used. When 20% of the total lot is nonconforming, this plan will indicate lot acceptance 33% of the time. Under resampling (pull a second sample of $n = 5$, $c = 0$ if the first sample indicated lot rejection), the chance of accepting a lot with 20% nonconforming units has increased from 33% to 55%.

5.7 STATISTICAL PROCESS/QUALITY CONTROL

Lot acceptance sampling plans are usually used to evaluate the quality of incoming and outgoing product. An integral part of HACCP will be monitoring on-line processes. Statistical Process/Quality Control (SPC/SQC) techniques have been developed, in particular control chart methodology, for this specific purpose.

Control charts enable:

- (1) CCPs to be monitored in an objective and consistent way;
- (2) Decisions on the process to be made with a measured degree of confidence;
- (3) Process control to be active and on-line, not passive; and
- (4) Primary applications on physical and chemical parameters, i.e. they need quick on-line feedback information, thereby precluding most microbial tests.

Under HACCP, appropriate and effective use of control chart techniques to monitor on-line CCPs will result in reduced end-product sampling. Control chart methodology is treated extensively in the SPC/SQC literature.

The following chapter deals with the practical aspects of monitoring. The standard operating procedures for sampling and examining shrimp for organoleptic and physical properties are explained in detail.

6 Sampling Procedures and Monitoring for Organoleptic, Physical and Chemical Quality

The importance of sampling in a HACCP program is established in the previous chapter. The actual procedures involved in the application of sampling and testing for organoleptic, physical and chemical characteristics of shrimp are described below. The schedule given in Table 6.1 is an example of how fresh and frozen shrimp are sampled for quality assurance purposes. The principles and procedures are similar when sampling is done during any stage of aquaculture.

6.1 SAMPLING SCHEDULE (IOM 616.62B(b) and 8 November 1984 memo from Dairy and Lipid Technology Branch, DFT, CFSAN (HFF-215))

Fresh shrimp: Examine a random representative (as shown in Table 6.1) portion of the lot to be evaluated.

Frozen shrimp: A representative (as shown in Table 6.1) number of packages, units or subdivisions should be collected on a code-by-code basis for organoleptic evaluation.

In general, frozen shrimp should be thawed in a spray of cold (50–70°F) water. In-shell shrimp will thaw quite quickly in a spray of cold tap water. When thawing commercially prepared packages of frozen shrimp, the analyst should always examine a minimum number of three units for net contents. For details see section 6.3.1 on physical testing for net contents of frozen seafoods. If the analysis of three units indicates a weight shortage, additional units should be examined. These samples are further subjected to organoleptic, microbiological and chemical tests, if required.

Table 6.1 Sample examination plan and legal action criteria

Lot size (No. of shipping cases)	No. of subs examined	No. of reject subs required for legal action
1–20	6	2
21–100	12	3
101 and above	18	4

These subs are to be collected from a minimum of three pallets but no less than the square root of the number of pallets. Inspectors are to view the entire lot or entries where stored and then select the pallets to be sampled from.

6.2 ORGANOLEPTIC ANALYSIS

Organoleptic or sensory analysis involves the employment of one or more of the physical senses (sight, touch, taste, smell) or subjective testing and rating of the food product in question. There are two categories of sensory tests:

- (1) Analytical or discriminative tests evaluate the differences or similarities and identify or quantify sensory characteristics and require trained or experienced panelists. Discriminative tests are often employed to determine raw shrimp quality.
- (2) Affective tests are used to evaluate preference and/or acceptance of the product and require a large number of untrained panelists who often represent a certain type of consumer. With proper experimental design, one can also obtain correlation between sensory and chemical or physical measurements from sensory analyses. This section provides a brief introduction to the subject.

6.2.1 Physical requirements of organoleptic examination

- (1) Work in an area that is free of distractions from other types of analyses.
- (2) Work in an area that is free of foreign odors:
 - (a) no smoking at any time;
 - (b) cosmetic odors should be avoided.
- (3) A slight positive pressure should be maintained in the testing area so that extraneous odors cannot enter the testing area. Proper ventilation also removes product odors.
- (4) Separate participants if possible. One person's reaction may affect another's judgment.
- (5) Lighting should be uniform, as near natural light as possible and not influence the appearance of the product being tested.
- (6) The product to be tested should be usually at room temperature or slightly above.

6.2.2 Other considerations

- (1) Special training is required for all inspectors to learn to differentiate certain off-odors listed below, several of which may be similar in odor.
- (2) Examine only one species or product at a time.
- (3) Take periodic rest breaks during the examinations.
- (4) Conduct all determinations independently of other examiners and immediately record results.

6.2.3 Procedure

- (1) Count or determine the number of individual units per container or package and record. In the case of very small units such as tiny shrimp (100–500/lb), count the number of shrimp per unit weight and calculate the number of shrimp per pound or package.

- (2) After the product is thawed, rinsed and brought close to room temperature, it is ready for organoleptic analysis.
 - (a) For large shrimp (0–100/lb): The flesh of each shrimp to be examined is broken into with the thumb and forefinger, and the freshly exposed muscle tissue is brought closely to the nose where it is smelled for odors of decomposition, and an organoleptic classification is made.
 - (b) For small shrimp (100–500/lb): Small portions, usually 2–3 oz, are taken and rubbed between the hands for a short period of time, then brought to the nose, smelled for odors of decomposition, and the portion classified. Check for any ‘off’ odors not typical of fresh headless shrimp.

Off-odor: No sour, musty, putrid, ammonia, fuel, etc.
Detectable level target: 0
Action level: < 0% shrimp
- (3) Identify the type of odor, its intensity (slight, moderate, marked, severe or excessive) and estimate the percent of shrimp affected of each intensity. Confirm off-odors by cooking shrimp in an enclosed container by boiling in water or with vent container in a microwave oven and cook by the standard procedure (section 6.3.5). Then, evaluate the sample to confirm off-odors or lack of them.

Fuel oil: Diesel oil or other petroleum product used by shrimp boats.

Chemical: Excessive sodium bisulfite, chlorine, etc. Chemical additives are not allowed in these products.

Biological: Bacterial odors, characteristic of the beginning stages of shrimp decomposition. They cover a wide range of off-odors: woody, fermented, unclean off-odors such as infected wounds, oniony, etc.

Sour: Typical sour odor as in pickled foods plus putrefaction. The first stage is distinguished by lactic acid odor and may be ammonia odor. The second stage exhibits stronger lactic acid with some putrefaction (indole, skatole odors). The third stage is strong lactic acid and strong putrid odor.

Musty: Ranges from an odor like fresh corn to an odor similar to mud or an ‘earthy-like’ odor. This occurs primarily in pond-raised shrimp when the salt level in the ponds drops below 10 parts per 1000. Blue-green algae growing in ponds under zero or low salinity will produce an ‘earthy-like’ substance in the water. When this material is absorbed in the shrimp flesh it cannot be washed away. The earthy-like-flavored material has been identified as geosmin, a high molecular weight alcohol. When there has been a great deal of rain in the area of the ponds, check the shrimp for musty off-odor before harvesting by sampling the ponds at areas of lowest water exchange, as on corners, etc. Check shrimp for musty odor by removing the shrimp head and breaking open the shell at one of the segments of the shrimp sampled, and immediately smell the exposed flesh. If musty odor is present, do not harvest immediately, pump salt water from the bottom of the estuaries at high tide and allow for two weeks of purging. Check again for musty off-odor before assuring that the musty shrimp flavor has been purged from the shrimp flesh.

Bilgy: Ranges from slight to moderate intensity off-odor and taste characterized by stale seawater or marsh-like odor and taste that is unpleasant. Cooking intensifies this off-odor.

6.2.4 Regulatory action guidance (FDA compliance policy guide 7108.05)

This aspect is pertinent to processors who import shrimp; therefore it becomes imperative to understand the criteria that trigger a detention. The guidance information on regulatory action allows the importer to develop appropriate product specifications (see Appendix 4).

The criteria used for direct seizure and for direct citation by the Food and Drug Administration (FDA) district offices involve organoleptic examination by two analysts which is further confirmed by indole determination (see section 6.4.3 under Chemical Testing). When the indole determination does not confirm the organoleptic finding, a qualified analyst in another District Laboratory will do a second organoleptic analysis on a duplicate sample. The results of both the original and check analyses shall be submitted to the Division of Regulatory Guidance with the recommendation for action. Regulatory action depends on the following criteria.

Criteria for decomposed subs

A sub shall be classified as decomposed if 5% or more of the shrimp are class 3; or if 20% or more of the shrimp are class 2; or if the percentage of class 2 shrimp plus four times the percentage of class 3 shrimp equals or exceeds 20%. Percentages are to be reported on the basis of either count or weight when the shrimp are uniform in size, and on a weight basis when the shrimp are nonuniform size.

Class 1 (Passable) – This category includes fishery products that range from very fresh to those that contain fishy odors or other odors characteristic of the commercial product; but these odors are not definitely identifiable as those of decomposition.

Class 2 (Decomposed) – Slight decomposition but definite. This is the first stage of definitely identifiable decomposition. An odor is present that is not really intense, but is persistent and readily perceptible to the experienced examiner as that of decomposition. Shrimp in this category are not acceptable for human consumption.

Class 3 (Advanced decomposition) – The product possesses a strong odor of decomposition, which is persistent, distinct and unmistakable. Shrimp in this category are not acceptable for human consumption.

Criteria used for confirming the presence of indole in shrimp

Two indole tests for each class of shrimp segregated by organoleptic examination. The three classes (if all classes are present) would preferably but not necessarily be taken from the same sub. Indole determinations confirm the organoleptic examination only when:

- (1) the indole level of each class 1 determination, which serves as an index for the accuracy of the organoleptic classification, is less than 25 µg per 100 g, and
- (2) the indole level of each class 2 determination equals or exceeds 25 µg per 100 g, and
- (3) the indole level of each class 3 determination equals or exceeds 50 µg per 100 g.

6.3 PHYSICAL TESTING

6.3.1 Net weight (CFR Title 50, Part 265.106)

For packages up to 5 lb, use a scale of adequate capacity with sensitivity of 0.01 oz. For those over 5 lb, use a scale of adequate capacity with sensitivity of 0.025 oz. Set the scale on a firm support and level. Adjust the zero load indicator and check the sensitivity.

Unglazed

Remove the package from low temperature storage. Remove frost and ice from outside of the package and weigh immediately (W). Open the package and empty the contents including any product particles and frost crystals. Air-dry the empty package at room temperature and weigh (E).

$$\text{Net weight of the contents} = W - E.$$

Glazed

Remove the package from low temperature storage, open immediately and place the contents under a gentle spray of cold water. Agitate carefully so the product is not broken. Spray until all ice glaze that can be seen or felt is removed. Transfer the product to a circular #8 sieve, 20 cm (8") diameter for 0.9 kg (2 lb) or less and 30 cm (12") for greater than 0.9 kg (2 lb). Without shifting the product, incline the sieve at an angle of 17–20 degrees to facilitate drainage and drain for exactly 2 min (use a stopwatch). Immediately transfer the product to a tared pan (B) and weigh (A).

$$\text{Net weight of the product} = A - B.$$

Frozen peeled shrimp blocks and packages

Place the contents of an individual package in a wire mesh basket. Immerse in a container of fresh water so that the top of the basket extends above water level. Introduce water at 80°F to the bottom of the container at a flow rate of 1–3 quarts per minute. As soon as the product thaws so that the glaze can be removed and the shrimp separated easily, transfer all material to a 12-inch sieve and distribute evenly. Tilt the sieve (about 20 degrees) and drain for exactly 2 min. Immediately transfer the shrimp to a tared container and weigh. Compare the shrimp weight to the stated package weight.

Approximate deglazing times for peeled and peeled undeveined (PUD) shrimp are shown in Table 6.2.

Table 6.2 Deglazing time v. temperature

Incoming water temperature (°F)	Time
70	2 h 30 min
72	2 h 23 min
74	2 h 16 min
76	2 h 10 min
78	2 h 5 min
80	2 h
85	1 h 49 min

For green headless, shell-on, subtract 1 h of time from the above chart. An example is given of a quick check of net weight on a portion of the block:

A 5-lb block of shrimp actually weighs 6 lb 4 oz (100 oz) including glaze. A piece of the block weighing 1 lb 8 oz (24 oz) is broken off the block. The 24 oz piece is deglazed as described above and it weighs 1 lb 4 oz (20 oz). The percent net weight = $20/24 \times 100 = 83\%$ of the sampled portion. Net weight of the block = $0.83 \times 100 = 83$ oz or 5 lb 3 oz. The stated net weight is 5 lb, so the block is acceptable.

6.3.2 Determination of the physical parameters

Count

Count the number of shrimp and record. Count the pieces, tailless and damaged and record. Count all whole shrimp within the unit and divide by the weight of the units minus the weight of the pieces, tailless and damaged, to determine the average count per pound.

Uniformity of size

- (1) Spread the sample on a large tray one layer thick.
- (2) Observe the visual appearance and separate all shrimp that are visually too small and too large for the appropriate size. Usually there are shrimp that by weight are 12–15% larger or smaller than the target range size.
- (3) Count how many are visually too large and too small and record the number. Then calculate the percentage of visually too large and too small.
- (4) Compare the results with the specification to see whether the sample meets or does not meet the specification.

Check for black spots, discoloration, dirty neck and cotton shrimp

Terminology

- (1) *Piece*: A shrimp piece is defined as one which appears to be at least one-half to two-thirds of a complete shrimp of the appropriate size.
- (2) *Tailless*: A tailless shrimp is defined as one without tail fins and telson, but which otherwise has substantially the same appearance as a complete shrimp of the appropriate size.
- (3) *Damaged*: A shrimp which is broken or cut in such a manner as to be unsuitable for further processing.
- (4) *Broken tail*: The tail shell portion composed of the fins and telson with or without the last segment shell and flesh. The presence of broken tails is objectionable.

Definitions of defects

- (1) *Black spot*: Melanosis on the flesh refers to blackened areas of 1/8" or larger in size on the flesh which are considered objectionable for peeled and deveined shrimp.

Black spot on flesh (applies to all shrimp):

- (a) *Slight*: Black spot < 1/8" on flesh on < 2 segments. At this level black spot on flesh is not objectionable for peeled and deveined shrimp. However, limit to < 15% by count.
- (b) *Moderate*: Black spot > 1/8" to < 1/4" on flesh on > 3 segments. This is objectionable and must not be present or it must be removed. Limit to maximum of 2% by count.

- (c) *Excessive*: Black spot $> 1/4''$ on > 3 segments. This is very objectionable and shrimp containing this level must be removed.
- (2) *Discoloration*: Chemicals cause discoloration. Sodium bisulfite turns the flesh of the shrimp yellow. Slight – tan, very pale yellow, just visible. Moderate – visible, light yellow discoloration. Excessive – deep yellow color that at times dissolves the shell. Shrimp of moderate and excessive levels are objectionable and must be avoided.
- (3) *Dirty neck*: This is caused by either chemical contamination (sodium bisulfite and chlorine), filth (dirt, grease, etc.) or enzymatic breakdown of pigment on the exposed neck of the flesh.
- (4) *Cotton shrimp*: Shrimp flesh is white due to a parasite in the flesh of shrimp. This causes an undesirable cotton-like appearance.
- (5) *Sand veins*: The presence of sand veins beyond the last shell segment is objectionable and must be avoided. There shall not be any shrimp containing a full vein; 4% or less is allowed for one segment vein or $\sim 3\%$ for two segment sand veins beyond the last segment shell.
- (6) *Extra shell*: Any extra shell or swimmerets left attached or loose on the shrimp is objectionable and must be avoided. Follow the same guidelines as above for this defect.
- (7) *Style defects*: Any peeling defects that are objectionable to the particular style being peeled. For butterfly tail-on (BF T-on) shrimp the presence of partial BF or round and buttonhole or side cuts are objectionable. For lightly dusted style (LDS), which is a $3/4$ -butterfly tail-on, the presence of complete round or BF T-on shrimp is objectionable.
- (8) *Rigid curling*: The degree of stiff curling due to rigor mortis. If the shrimp has a slight to moderate degree of curling, it is not objectionable. However, stiff curling is objectionable at marked and excessive or severe levels. Marked and excessive (severe) rigid curled shrimp make a finished product with poor plate appearance as well as inferior eating quality due to excessive, not fully cooked, gummy batter and breading accumulated at the inside bend of objectionable curled shrimp. In addition, Ring & Prince Seafood Corporation must meet its customer's product specification; therefore, a 12% action level of objectionable rigid curling has been set for peeled shrimp (raw material).
- (9) *Extra flesh*: The portion of flesh that is left attached to the first segment when the shrimp head is removed. See below for examples of extra flesh shrimp. Target 0% and action level $> 1\%$.
- (10) *Dehydration*: Physical appearance is dry and cotton-like. Caused by freezer burn, which is a result of a poor glaze, fluctuating freezer temperature, thaw damage or old product.
- (11) *Soft/mushy texture*: Check for soft or mushy texture of shrimp by properly cooking them according to standard procedures (Appendix 6). A good cooked shrimp texture is characterized by a crisp, firm, but tender and moist mouth feel as opposed to soft or mushy, doughy, stringy or dry mouth feel. The causes of shrimp texture deterioration are tenderizing (proteolytic) enzymes present in shrimp flesh tissue and conditions brought about by the mishandling of shrimp. Causes of soft or mushy texture are too long a delay at warm temperatures before removing the shrimp head, which has strong

tenderizing enzymes that spill and permeate the shrimp flesh, or the addition of fig leaves or proteolytic enzymes. Also, the treatment of shrimp with milk or soy protein isolate may cause soft or mushy texture of the shrimp.

(12) *The presence of undesirable species:*

- (a) *On peeled and deveined (PD) Penaeus shrimp:* The presence of non-*Penaeus* shrimp or monodon shrimp is unacceptable. Target 0% by count of objectionable shrimp species for peeled and deveined shrimp.
- (b) *On peeled and undeveined (PUD) T-on shrimp:* The presence of deepwater tiger or big head shrimp is objectionable. Limit deepwater tiger and big head shrimp to < 10% by count.

If the product meets the purchase specifications (see Appendix 4), proceed with other tests as required.

6.3.3 Determination of filth in shrimp (FDA regulatory procedures manual, Part 9 – Imports)

Frozen shrimp can either be partially thawed in its own container at refrigerator temperature or analyzed directly from frozen storage without prethawing. Fresh (unfrozen) product may be analyzed directly from the container. Place 2–2.5 lb of product on a 12-inch diameter #8 mesh sieve nested on top of a 12-inch diameter standard #140 mesh sieve. Wash the product thoroughly with a forced stream of hot water. Product frozen into blocks must be washed until all ice has melted. After washing, visually examine the product on top of the #8 sieve for macroscopic filth and extraneous material. Remove and preserve the macroscopic adulterants from the #8 sieve. Quantitatively transfer the material retained on the #140 sieve to a 1-l trap flask using a stream of water. Trap off using water and 30 ml heptane. If a small amount of material is retained on the #140 sieve, the retaining may be quantitatively transferred directly from the sieve on to the filter paper without trapping. Examine filter papers at 30×–60× magnifications. Report the combined findings of the microscopic and macroscopic results.

Guidelines for interpretation of results (these guidelines do not include all types of filth or the different combinations of filth that may be found in shrimp)

Samples of imported fresh or frozen raw shrimp may be detained when analysis of six 2–3 lb subs shows filth at or above the following levels:

- (1) Flies (whole or equivalent)
 - * Filth flies – two in a sample
 - ** Incidental flies – ten in a sample
- (2) Filth flies fragment
 - (a) Three fragments (excluding setae) in five of the six subs (these fragments are clearly identified as parts of a filth fly)
 - (b) Large body parts (that is, thorax, abdomen) – one in three of six subs
- (3) Cockroaches
 - (a) One whole or equivalent in the sample
 - (b) Excreta – one in two of six subs

- (4) Hairs
 - (a) Rat or mouse – three of any size in a sample
 - (b) Striated but not rat or mouse – four of any size in a sample

Recent FDA interpretations include detention of imported shrimp if contaminated with ants. Determinations of the significance of the presence of these filth elements in shrimp are made on a case-by-case basis.

- * Filth flies: houseflies (Muscidae), humpbacked flies (Phoridae), moth flies (Psychodidae), black scavenger flies (Sepsidae), small dung flies (Sphaeroceridae), chloropid flies (Chloropidae), anthomyid flies (Anthomyiidae), blow flies (Calliphoridae) and flower flies (Syrphidae). This is not necessarily a complete list of filth flies that might be found in shrimp.
- ** Incidental flies: dance flies (Empididae), beach flies (Canacidae), shore flies (Ephydriidae), Natchiidae, tachinid flies (Tachinidae). This is not necessarily a complete list of incidental flies that might be found in shrimp.

6.3.4 Flesh content of frozen breaded shrimp

Weigh each unit while it is hard frozen. Using clip tongs, place each portion or stick individually in a water bath maintained at 17–49°C (63–120°F) until the breading becomes soft (5–110 s for portions held in storage at –18°C (0°F)). Breading can be easily removed from the still frozen flesh with a round tip spatula or a table knife. Limit the dip time to 15 s when temperatures are greater than 100°F. Remove the portion and blot lightly with double thickness paper towel. Complete this step in less than 7 s. Scrape and remove breading and batter from flesh with a spatula, removing material from narrow sides and ends in initial movements followed by removal from side flat surfaces. If breading is difficult to remove, re-dip the partially de-breaded portion in water at room temperature for about 2 s. Blot with a towel and remove residual batter and breading material. Reweigh the de-breaded portion and record. Calculate using the formula:

Percent flesh = (Weight of de-breaded flesh × 100)/Weight of the original unit.

Several preliminary trials may be necessary to determine the dip time required for de-breading sample units. For these trials only, prepare a saturated solution of copper sulfate 450 g (1 lb)/2 l tap water. The correct dip time is the minimum time of immersion in copper sulfate solution required before breading can be easily scraped off, provided that de-breaded portions are still solidly frozen, and only a slight trace of blue color is visible on the surface of de-breaded portions. As a guide, use lower temperatures with raw and higher temperatures with precooked products.

6.3.5 Standard cooking procedure

The purpose of cooking is to check the texture and eating quality of shrimp, cooked by the following standard procedure.

Methods of cooking the product include, but are not limited to, baking, bake-in-foil, broiling, boil-in-bag, shallow pan frying, deep fat frying, oven frying, grilling, poaching, steaming and microwave heating.

Table 6.3 Simmering time chart*

Style	Peeled from	Simmering time (min)
G.H	U/15	3.25
PD T-on	16/20	3.00
PD T-on	21/25	2.75
PD T-on	26/30	2.50
PD T-on	31/35	2.00
PD T-on	41/50	1.75
PD T-on	51/60	1.50
PD T-on	61/70	1–1.25
PD T-on	71/90	1–1.25
PD or PUD	91/110	1–1.25
PUD	100/200	1–1.25
PUD	200/300	0.75–1.00

* This is only a guideline. One has to develop a chart for each of the species handled.

- (1) Measure 1l of water for 8 oz (227 g) of shrimp sample. Use a 3 quart aluminum pot or equivalent.
- (2) Add 20 g salt for 8 oz of shrimp and bring to full boil.
- (3) Drain peeled and deveined (unfrozen) shrimp for 2 min.
- (4) Weight approximately 227 g (about 8 oz); record the weight.
- (5) Add weighed shrimp to heated water and bring to near a boil (200°F). Use a thermometer. The cooking procedure is based on heating the product to an internal temperature of a minimum 70°C (160°F). Cooking times vary according to the size of product and equipment used.
- (6) When the temperature reaches 200°F, remove the pot from the heat and allow simmering for the length of time designated for that particular size (see Table 6.3) maintaining 200°F in the pot with water and shrimp.
- (7) When time is up, cool immediately by placing the shrimp on a wire mesh draining rack and run cool tap water over them until the shrimp cool to about 90°F or below.
- (8) Allow draining for 2 min.
- (9) Immediately weigh out accurately and record weight for cooking yield if yield is desired.
- (10) Evaluate shrimp odor, texture and flavor by sensory methods. Cooking equipment, including cooking oil for deep fat frying, shall be free from substances that interfere with sensory evaluation of the cooked product.
- (11) Count the number of shrimp with slight, moderate, severe (excessive) off-odor, soft or mushy texture and off-flavor. Express in percentage.

6.4 CHEMICAL TESTING

The test procedures chosen here are based on their simplicity and ease, and commonly available equipment. Rapid test procedures are included wherever they are available and applicable.

6.4.1 Phosphorus (phosphates)

Shrimp is sometimes treated with phosphates (sodium tripolyphosphate, STPP) to improve water retention in the flesh during freezing/thawing. It is a legal additive and its use must be shown in the product's ingredient list. This procedure measures total phosphorus in a food sample. To determine added phosphorus, naturally occurring phosphorus has to be known and deducted from the total phosphorus.

Chemicals

- (1) Dilute nitric acid: One volume of concentrated nitric acid diluted with four volumes of water.
- (2) Quimociac reagent: Dissolve 70 g sodium molybdate dihydrate in 150 ml water. Dissolve 60 g citric acid monohydrate in a mixture of 85 ml of concentrated nitric acid and 150 ml water and cool. Gradually add the molybdate solution to the citric–nitric acid solution while stirring. Dissolve 5 ml synthetic quinoline, with stirring, in a mixture of 35 ml of concentrated nitric acid and 100 ml water. Gradually add this solution to the molybdic–nitric acid solution, mix well and let stand for 24 h. Filter, add 280 ml acetone, dilute to 1 liter with water and mix. Store in either a noncolored polyethylene bottle or a dark brown glass bottle.

Procedure

- (1) Prepare filter crucibles the day before by weighing to a constant weight. Weigh the filter crucible, place in a drying oven (125°C) for about 1 h and transfer to a desiccator to cool. Reweigh the crucible, and continue this procedure until there is less than 0.0004 g difference between weighings.
- (2) Weigh the ashing crucible, add approximately 2.5 g of frozen sample; reweigh the crucible with sample and subtract the crucible weight to get the actual sample weight (weigh to four decimal places).
- (3) Place the crucible with sample in a 125°C force-draft oven for 30 min along with the crucible cover, but do not cover the crucible while drying.
- (4) Remove and place the crucible with cover on in a muffle furnace at 550°C to ash until a white or nearly white ash is obtained.
- (5) Cool the crucible in a desiccator. Using a pipette, add 25 ml of dilute nitric acid making sure to rinse ash from the sides of the crucible. Heat on a steam bath for 30 min (turn on the steam bath about 2 h in advance).
- (6) Filter the solution through Whatman #1 paper into a 400 ml beaker using a glass rod to guide the solution. Thoroughly wash the crucible, paper and glass rod with distilled water so that the total volume in the beaker is approximately 100 ml.
- (7) Run a reagent blank in parallel, using 25 ml of dilute nitric acid and 75 ml distilled water.
- (8) Add 50 ml quimociac reagent to each beaker, cover with a watch glass and boil for 1 min. (Do not use an open flame.) Cool to room temperature, swirling occasionally.
- (9) Carefully transfer the precipitate (using a glass rod) to the prepared filter crucible (brought to constant weight). Filter using suction.

Table 6.4 Phosphates and their corresponding factors*

Phosphate	Factor (F)
Na_2HPO_4	4.58
NaPO_3	3.29
$\text{Na}_5\text{P}_3\text{O}_{10}$	3.96
$\text{Na}_4\text{P}_2\text{O}_7$	4.29
NaH_2PO_4	3.87
$\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$	3.58
P_2O_5	2.29

*Developed by Dr Fred King, NMFS, Gloucester, MA. AOAC 14th edn, #24.016.

Note: If phosphate is unknown, calculate and report as sodium tripolyphosphate ($\text{Na}_5\text{P}_3\text{O}_{10}$).

- (10) Wash the precipitate five times with 25 ml portions of water. Allow each portion to drain most of the water out before adding the next. Be sure to use water to wash the beaker and glass rod.
- (11) Dry the crucible and contents for 30 min at 250°C (or overnight at 125°C). Cool in the desiccator and weigh to a constant weight as before within 0.0004 g differences.

Calculations

$$\text{Phosphorus content} = (100) (A-B) (0.014) - (0.0106) (\% \text{ meat protein}) / C$$

Gravimetric factor 0.014 is derived from the following:

Atomic weight of phosphorus = 30.97

Molecular weight of QPM: $(\text{C}_9\text{H}_7\text{N})_3 \text{H}_3\text{PO}_4 \cdot 12\text{MoO}_3 = 2212/71$

P/QPM = 0.014

0.0106 = Factor to correct for the phosphorus content of meat protein.

Phosphate content = phosphorus content $\times$ F* (see Table 6.4 for F values)

Wherein,

$$F = \text{anhydrous molecular weight of the desired phosphate} / (\text{X})(\text{atomic weight of phosphorus}).$$

Where X = Number of atoms of phosphorus in one molecule of phosphate.

A second colorimetric method (972.22, AOAC, 1990) involves reacting phosphate and molybdenum ions in acid solution to produce 12-molybdophosphoric acid, which is then reduced with 1-amino-2-naphthol-4-sulfonic acid to phosphomolybdenum blue. Maximum absorption at 660 nm is proportional to the amount of phosphorus present. This method is applicable to 0.05–0.4% phosphorus.

6.4.2 Sulfites

Shrimp melanosis is commonly termed ‘black spot’. It is a surface discoloration caused by enzymatic formation of precursor compounds that can polymerize

spontaneously and/or react with cellular constituents to form insoluble pigments. The result is formation of black spots similar to browning in apples or potatoes. The endogenous shrimp enzyme, polyphenol oxidase (PPO), catalyzes the initial step in black spot formation and remains active throughout post-harvest processing unless the shrimp is frozen or cooked. Sulfiting agents such as sodium metabisulfite inhibit black spot formation and were introduced in the 1950s. Present regulations for the treatment of shrimp are a 1-min dip in a 1.25% (12 500 PPM) sodium metabisulfite solution with an allowable sulfite residue of 100 PPM in the shrimp meat. Currently, this dip procedure is employed on commercial vessels followed by storage on crushed ice or brine freezing of the sulfited shrimp for subsequent transport and handling. Some shrimp aquaculture facilities are using sulfites to treat pond harvests. Under the Federal Food, Drug and Cosmetic Act (US), foods that contain preservatives such as sulfites must bear labeling stating that fact. Sulfites can cause allergic reactions in asthmatics and other sulfite-sensitive individuals.

Recent research indicates a 1-min dip in 0.005% (50 PPM) 4-hexylresorcinol as a functional alternative to sulfites. One proprietary blend of 4-hexylresorcinol (Everfresh™ Melanosis Inhibitor for the prevention of blackspot) is available in weatherproof pouches. This product is manufactured by Opta Food Ingredients, Inc., Cambridge, MA 02139. Each pouch contains a premeasured amount of inhibitor for use in a 3-gallon dip tank.

- (1) Sulfite-test strips that give rapid and quantitative results are available from the following manufacturers:
 - (a) Quantofix sulfite (0–1000 PPM) is available from Macherey-Nagel, Duren, Germany.
 - (b) EM Quant (0–400 PPM) is available from E. Merck, Darmstadt, Germany. (Follow the manufacturer's directions for use.)
- (2) Malachite green (qualitative) test:
 - (a) Reagent: Tablets for preparation of 15 ml reagent are available from LaMotte Chemical Product Co., P.O. Box 329, Chestertown, MD 21620. Malachite green solution: Dissolve 200 mg malachite green (certified by Biological Stain Commission) in water and dilute to 1 l. Solution is stable for several weeks if dispensed from a poly dropper bottle assembly with a Neoprene bulb. Discard when visible deterioration occurs.
 - (b) Procedure: Transfer about half a teaspoonful (3.5 g) of ground meat to a waxed white freezer paper or any impervious surface. Add 0.5 ml reagent and mix vigorously for 2 min with a spatula. Normal meat attains a bluish-green color. Observe the color after a few minutes. Decolorization of the meat indicates the presence of sulfites. Verify positive results by Monier-Williams method, AOAC 962.16C (AOAC, 1990).

6.4.3 Indole test for decomposition (Cheuk and Finne, 1981)

Among numerous methods suggested as chemical quality indices of fresh and frozen shrimp, the determination of indole has recently attracted much attention. Even though indole was studied as an index of shrimp quality as early as 1946, it was only recently that the FDA proposed the use of indole levels as an indicator

of decomposition in imported shrimp. In support of organoleptic testing, indole has already been used as a decomposition indicator in the seizure of frozen salad shrimp.

It is generally believed that indole is present in shrimp as a result of bacterial activity before freezing. The numerical levels for indole tolerances that correspond to organoleptic tolerance levels of decomposition have been established.

Traditionally, indole in seafoods has been determined by a colorimetric method that involves a time-consuming steam distillation with subsequent cumbersome extraction of the distillate. More recent methods include gas-liquid chromatography, fluorometric analysis and liquid chromatography/fluorometry. The latter three methods require well-trained personnel and sophisticated and expensive instrumentation, and are therefore not suitable as a quality control method for implementing HACCP.

The following method describes a rapid modified colorimetric procedure, which is simple, and a convenient alternative to the official steam distillation colorimetric procedure, shortening the analysis time from approximately 4 h to 1 h per sample. This modified method takes advantage of using immiscible indole solvents for separation and purification rather than steam distillation.

Chemicals and equipment

- (1) Ehrlich's reagent: Dissolve 9 g ACS grade para-dimethylaminobenzaldehyde (PABA) in 45 ml concentrated HCl in 250 ml volumetric flask and dilute to volume with ethanol.
- (2) Standard indole solutions: Accurately prepare stock solution of 10 mg indole in 100 ml light petroleum. Use 1 : 10 dilution as a working solution. Refrigerate indole solutions.
- (3) Petroleum ether BP (37.1–57.5°C).
- (4) Refrigerated centrifuge.
- (5) Trichloroacetic acid (TCA): Accurately weigh 6 g of TCA in 100 ml distilled water.
- (6) A double beam grating spectrophotometer.

Procedure

Homogenize 40 g shrimp with 80 ml TCA solution in a Waring blender for 1 min. Add 80 ml ice-cold petroleum ether and blend for 1 min. Transfer the homogenate to a 250 ml centrifuge bottle and centrifuge at 10 000 rpm for 10 min. Filter the supernate through Whatman #1 paper under slight suction. Transfer the filtrate to a 250 ml separatory funnel. After the two layers have separated, transfer the acid layer (lower) to a second separatory funnel. Wash TCA denatured protein precipitates separated by centrifugation with 40 ml of petroleum ether and filter once again. Transfer the filtrate to the separatory funnel containing the TCA layer from the first extraction. Shake vigorously for 1 min and let the two layers separate. Transfer the lower acid layer to a third separatory funnel and extract for a third time with 40 ml light petroleum. Combine all light petroleum extracts into one separatory funnel and extract indole with exactly 5 ml freshly prepared Ehrlich's reagent by vigorously shaking for 1 min. The indole in the petroleum fraction reacts with the aldehyde in the Ehrlich's reagent to form the rose colored indole complex which is insoluble in light petroleum and thus gets quantitatively transferred to Ehrlich's reagent layer. When the layers have separated and cleared, transfer part of the

lower colored layer to a cuvette and read at 570 nm against a reagent blank. If this complex is not clear, centrifuge at lower speeds before reading in the spectrophotometer. Determine the indole concentration from an indole standard curve prepared from indole standard solution. The rose indole complex from indole standard and from TCA extracted shrimp is stable for about 4 h and is not affected by the intensity of normal laboratory illumination.

Preparation of the standard curve: For pure indole, accurately measure volumes from 0.5 to 4.0 ml (5–40 μ g) stock indole solution into 80 ml TCA in a separatory funnel. Re-extract indoles by the procedures described above and construct a standard curve.

The following chapter describes various procedures used in monitoring the microbiological quality of shrimp.

7 Monitoring for Microbiological Quality

7.1 INTRODUCTION

Microbiological testing is often used as a verification tool to establish that the overall operation is under control. Physical and chemical measurements are the preferred monitoring methods since microbiological methods are often time consuming. However, the future seems to be promising, as rapid microbial detection (for some pathogens such as *Salmonella* and *Listeria*) is becoming available at a reasonable cost. This chapter introduces the basic concepts of microbiology. The latter part of the chapter describes actual experimental protocols used in screening or enumerating for those microorganisms that are of interest to the shrimp processor.

7.1.1 What are microorganisms?

These are microscopic in size, ubiquitous in their distribution, practically in every environment, and they adapt to almost every growth condition. Microorganisms require water and nutrients for their survival and growth. They include the following groups:

- (1) viruses (smallest);
- (2) bacteria: prokaryotic, unicellular organisms ranging from 0.2 to 8.0 μm ; 1–2 μm being the average size. They come in different shapes: rod-shaped, bacilli; spherical, cocci; and spiral shaped, spirilli;
- (3) yeasts;
- (4) fungi/molds; and
- (5) protozoa.

7.2 FEATURES THAT ARE UNIQUE TO MICROORGANISMS

- (1) Microorganisms are so small that most of them must be magnified about 1000 times before they can be seen even with a microscope. This thousand-fold magnification of an average person would result in his attaining a size of more than one mile in height and a width of about one quarter mile.

For example, *Escherichia coli*, a bacterium: 400 million of them could fit into the space taken by a grain of sugar. It also means that one cubic inch space can theoretically contain more than 10 billion (10 000 000 000/cubic inch) bacteria.

- (2) Each doubling requires about 20 min. Microorganisms grow exponentially, producing large numbers in small volume – from one cell to over 1 000 000 in 20 doublings and over 1 000 000 000 in 30 doublings. Such phenomenal growth rates result in serious effects, causing the foods to spoil and leading to sickness

if the microorganisms growing in the food happen to be pathogenic. Note: the mere presence of pathogens (such as *Salmonella* or *Listeria*), regardless of numbers, constitutes a health hazard.

7.3 FACTORS THAT INFLUENCE THE GROWTH OF MICROORGANISMS

There are a number of external and internal factors (intrinsic to the *substrate*, that is, the foods in which they grow) that affect the microbial growth (Kanduri and Hudak-Roos, 1993c).

7.3.1 External factors

Of the different external factors, temperature is the most important one.

- (1) Thermophiles (high-temperature loving kind): growth optimum above 45°C (35–65°C).
- (2) Mesophiles (medium-temperature loving kind): growth optimum 25–37°C (15–45°C).
- (3) Psychrotrophs (cold-temperature tolerant kind): growth optimum 25–37°C (3–40°C).

7.3.2 Internal factors of the substrate

- (1) Water activity (A_w): A measure of the amount of water that is readily available for the growth of the microorganisms. The A_w for pure water is 1.0.
- (2) pH: While microorganisms grow over a wide range of pH, most bacteria grow optimally at pH near neutral. Yeast and fungi can grow under more acidic conditions.

7.3.3 Interaction between growth factors

- (1) Some microbial growth occurs when one of the factors controlling the growth is limiting. For example, bacterial growth slows down under reduced pH or acidic conditions.
- (2) If more than one factor becomes limiting, microbial growth is drastically curtailed or even stopped. For example, bacterial growth would stop under acidic conditions combined with low temperature and lower A_w .

7.4 MICROORGANISMS AND THEIR EFFECT ON HUMANS

Of the numerous variety of microorganisms found in nature, a majority are beneficial to humans. This can be seen readily in compost production, cheese production, pickles, production of various antibiotics (from fungi or molds), and fermentation of beer and wine. Fortunately, only a few kinds of microorganisms are pathogenic in nature. Such pathogenic microorganisms produce or contain toxins which, when released into the food or in the human system, cause illness. The resulting illness can range from having minor to lethal effects on humans and animals.

7.4.1 Pathogenic

Microorganisms which are pathogenic in nature and their effect on consumers

The pathogenic kind of microorganisms release toxins into the substrate (food or directly into the human gastrointestinal system) and could cause the following:

- (1) *Intoxication*: Toxins are preformed in the food as a result of microbial growth.
For example: *Staphylococcus aureus* (toxins causing diarrhea or vomiting); *Clostridium botulinum* (neurotoxins causing paralysis).
- (2) *Infection*: Live cells or viable spores of pathogen must be ingested and grow in the body. There are two types of infection: invasive and non-invasive.
 - (a) *Invasive*: those types of microorganisms that attack the mucosal linings, resulting in tissue destruction. Pathogens can also invade underlying cells, other tissues, or cells associated with the immune system.
For example: *Salmonella*, *Listeria monocytogenes*, *Shigella*, some *E. coli*, *Yersinia* and *Campylobacter*.
 - (b) *Non-invasive*: those types of microorganisms that are usually enterotoxigenic, that is, producing toxins in the intestinal tract. This type of infection is caused by the attachment of the ingested bacteria to the small intestine, and toxin is released into the intestinal tract.
For example: *Vibrio cholera*, *Vibrio parahemolyticus*, some *E. coli*, *Bacillus cereus*, *Clostridium perfringens*.

The resulting effect of pathogenic microorganisms on humans can potentially:

- (1) Be lethal due to toxins produced in the food leading to death after consumption.
- (2) Lead to serious illness – may lead to death, especially in vulnerable groups of populations.
- (3) Cause minor illness – may lead to death if not properly treated.
- (4) Have long-term effects – such as reactive arthritis; specific tissue damage (liver, kidney, etc.); cancer – mycotoxins.

7.4.2 Spoilage causing

The second group of microorganisms simply cause spoilage without causing illness. These result in spoilage in the foods and lead to:

- (1) Reduced shelf life.
- (2) Loss of product leading to waste and increased cost.

7.5 CLASSIFICATION OF BACTERIA

7.5.1 Stain

Based on the stain they retain when a smear is subjected to a differential stain, bacteria are classified as either Gram-positive or Gram-negative.

Gram staining procedure: Stain the smear with crystal violet, decolorize with acetone/alcohol (30 : 70) mixture, and restain with safranin. Due to the differences in

the chemical composition of their cell envelopes, Gram-positive bacteria retain the crystal violet and appear purplish-blue under the microscope. Gram-negative bacteria lose the crystal violet during the decolorizing step, and allow the saffranin to stain the bacteria. Thus Gram-negative bacteria appear pink in color.

7.5.2 Based on their oxygen requirements

- (1) Aerobic microorganisms – oxygen is toxic.
- (2) Microaerophilic microorganisms – reduced oxygen tension, approximately 5%.
- (3) Facultative anaerobes/aerobes – have the ability to grow either in the presence or absence of oxygen.

7.6 MICROBIOLOGICAL TESTING PROCEDURES

Traditional microbiological testing is ineffective for routine monitoring. However, the latest developments in rapid microbial and hygiene testing for food-borne pathogens allow production and sanitation to ensure cleanliness and employee performance. Modern techniques for rapid microbial detection (RMD) are largely based on four principles:

- (1) immunological analyses;
- (2) nucleic acid probes and polymerase chain reaction (PCR);
- (3) electrical conductance and impedance; and
- (4) biochemical and enzymatic profiling.

For most food-borne pathogens, immunological tests are applied after 24–48 h of enrichment. Some are as lengthy as 96 h, others as quick as 10 min. For testing the sanitary conditions, RMD allows quick monitoring that gives microbial load and degree of soiling at a sampling site in less than 1 min.

The currently available rapid microbiological testing procedures are listed below. These procedures facilitate timely monitoring and implementation of a HACCP system in sanitation, culture and processing operations. In cases where more than one kind of rapid method is available, one of the methods is explained in detail as an example and the other methods are listed for reference purposes. Some of the rapid tests are only used as screening methods for detecting the presence or absence of particular pathogens (for example, *Salmonella* and *Listeria*). In such cases, the samples testing positive from rapid tests must be confirmed using standard plating procedures.

7.6.1 Standard plate count (SPC)/total viable count (TVC)/total plate count (TPC)/aerobic plate count (APC)

Background

The flesh of newly caught healthy shrimp is generally considered to be sterile. The number of bacteria in freshly caught species may usually range from 10^3 to $10^4/\text{cm}^2$, or per gram of the fish tissue. SPC, TVC, TPC and APC are terms used interchangeably. The term means the number of organisms that when taken out of the fish would develop into clearly visible colonies under standard conditions and procedures.

There is no correlation between SPC and the eating quality or between SPC and the presence of pathogenic bacteria in the fish. Therefore, SPCs are limited in value as a quality control tool. However, SPC may give a comparative measure of the overall degree of microbial contamination and sanitation applied during fish handling and processing.

Recent developments in RMD: Bacteriological tests are laborious, costly and time-consuming, and require skills in the execution and interpretation of the results. The hygiene/cleanliness kits available for monitoring sanitation include BioOrbit (Diagnostix, 1238 Anthony Rd, Burlington, NC 27215); Uni-Lite (Biotrace/Ecolab, 370 Wabasha St. N, St. Paul, MN 55102); Methoxy pH electrode and the ATP analyzer (Cypress Systems, 2500 W 31 St., Ste D, Lawrence, KS 66047); Lightning (IDEXX, One IDEXX Dr., Westbrook, ME 04092); SystemSure (Celsis, 4270 US Rte. One, Monmouth Junction, NJ 08852); BG-P (GEM Biomedical, 925 Sherman Ave., Hamden, CT 06514); Ribo-Printer (DuPont); Biocounter (Perstorp Analytical, 12101 Tech Rd., Silver Spring, MD 20904); and BacT/Alert (Organon Teknika, Akzo Nobel Salt, 100 Akzo Ave., Durham, NC 27712). The principle of ATP bioluminescence is being used by most of these companies. For example, Uni-Lite is a chemical test, which measures all organic, not just microbial contamination. It is based on the principle that all living things contain adenosine triphosphate (ATP), and that the amount of ATP on a surface is proportional to the amount of contamination. After swabbing the samples are treated with two reagents that dissolve the cell membrane and cause the exposed ATP to luminesce. The testing instrument then measures the amount of bioluminescence, indicating the level of cleanliness. Such a system eliminates the material cost of agar, the time to make and pour plates and the space needed to incubate the plated samples.

Information pertaining to rapid microbiological test kits is available on the Blackwell Publishing website and other websites such as University of California's Seafood Network Information Center.

Ready-to-use Petrifilms (3M Microbiological Products, 3M Center, Bldg 275-5W-05, St. Paul, MN 55144) are available at a reasonable cost. The following procedure describes test performed using Petrifilm Plates sold in a ready-to-use form.

Objective

To detect bacterial contamination through direct contact or swab contact of the surfaces using '3M Petrifilm' Aerobic Count Plates.

Materials and equipment

Sterile diluent (Butterfield's buffer or 0.1% peptone water)

Dilution tubes with sterile diluent

Sterile cotton swabs

Petrifilm plates (3M)

1 ml serological pipettes

Incubator

Procedure

- (1) Prehydrate Petrifilm plates with 1 ml of appropriate sterile diluent (Butterfield's buffer or 0.1% peptone water). See instructions in the package insert. Allow a minimum of 30 min for the gel to solidify on the Petrifilm plates, before using the plates for surface sampling.

- (2) Store the prehydrated Petrifilm plates in a pouch or plastic bag sealed with tape. Protect plates from light by wrapping and refrigerate. Such refrigerated and prehydrated plates may be used for up to one week after hydration.
 - (a) Direct contact (surface method): Lift the top film portion of the prehydrated plate carefully, without touching the circular growth area. Allow the circular gel portion of the top film to contact the surface being tested. Rub the fingers over the outer film side of the gelled area to ensure good contact with the surface. Lift the film from the surface and rejoin the top and bottom sheets of the Petrifilm plate.
 - (b) Indirect contact (swab method): Open a sterile dilution tube. Moisten the swab head and press out excess solution against the interior wall of the vial with a rotating motion. Rub the swab slowly and thoroughly over the desired surface area. Break off the swab head into the dilution tube and replace the cap. Shake the tube vigorously for 10 s. Inoculate the Petrifilm plate with 1 ml of the solution.
- (3) Incubate the plates with the clear side up in stacks of 20 or fewer at 20°C for 48 h and read them on the Quebec-type colony counter. (Please refer to the *Guide to Interpretation*, the company's colored brochure, when reading the results.)

7.6.2 Total coliform and *E. coli* counts

Background

Coliform (total) organisms are aerobic to facultatively anaerobic, nonspore-forming Gram-negative rods which ferment lactose with the production of acid and gas at 32–35°C within 48 h. Coliforms (*Escherichia*, *Enterobacter*, *Citrobacter* and *Klebsiella*) are used as an indicator of post-harvest contamination, particularly of fecal origin. A majority of them are harmless, with the exception of a few strains of *E. coli*, which have limited pathogenicity in the aged and infants. One such example is *E. coli* 0157:H7. International Bioproducts (PO Box 2728, Redmond, WA 98073) and Neogen Corp. (620 Leshner Place, Lansing, MI 48912) are examples of companies that have developed preliminary screening test kits specifically to detect *E. coli* 0157:H7 strain.

E. coli is a normal inhabitant of the intestinal tract of humans and other warm-blooded animals. Therefore, its presence outside the intestines, in food or water, might be regarded as evidence of poor sanitary conditions. *E. coli* is sensitive to sub-zero temperatures and therefore unsuitable as an indicator of fecal contamination in frozen fish.

Objective

The objective is to enumerate total coli-forms and *E. coli* in the given food sample using the 3M Petrifilm plates sold in a ready-to-use form.

Materials and equipment

Sterile diluent (Butterfield's buffer or 0.1% peptone water)

Whirl-pac bag

Stomacher bag or appropriate sterile container

Coli count plates (3M)

ml serological pipettes

Top-loading balance

Incubator

Procedure

- (1) Weigh or pipette (1 : 10 or more dilution) the food product into the sterile container.
- (2) Add appropriate quantity of diluent.
- (3) Blend or homogenize the sample.
- (4) Place the Petrifilm plate on a flat surface.
- (5) Lift the top film; with pipette perpendicular to the plate, place 1 ml of sample onto the center of the bottom film.
- (6) Carefully roll the top film down to avoid entrapping air bubbles. *Do not let the top film drop.*
- (7) With the flat side down, place the spreader on the top film over the inoculum.
- (8) Gently apply pressure on spreader to distribute inoculum over the circular area. *Do not twist or slide the spreader.*
- (9) Lift the spreader. Wait for 1 min for the gel to solidify.
- (10) Incubate the plates with the clear side up in stacks of 20 or fewer at a temperature of 32–35°C for 24–48 h.
- (11) Coliform counts: Count coliform colonies from coliform count plates using a Quebec-type colony counter.

Coliforms produce red colonies that are associated with gas bubbles (a red indicator dye in the plate colors all colonies and the top film traps gas produced by the coliforms). (See Appendix 7.)
- (12) *E. coli* counts: Count *E. coli* colonies from coliform count plates using a Quebec-type colony counter.
 - (a) Count the blue colonies associated with gas bubbles as confirmed *E. coli* (they produce glucuronidase that reacts with an indicator dye in the plate to form a blue precipitate around the colony).
 - (b) Non-*E. coli* coliforms form red colonies and are associated with gas bubbles. Count all red and blue colonies with gas to obtain a total coliform count. (Please refer to the *Guide to Interpretation*, the company's colored brochure, when reading the results.)

Note: AOAC Official Method (998.08) approval for 3M Petrifilm *E. coli*/coliform count plates was granted for the determination of confirmed *E. coli* in poultry, meat and seafood. These tests can be read after 24 h of incubation in meat, poultry and seafood.

7.6.3 *Salmonella* spp.

Background

Salmonella is a rod-shaped, motile, nonspore-forming and Gram-negative organism. It is widely present in all warm-blooded animals. There are over 2000 *Salmonella* serotypes known. The organism has been found in water, soil and insects, on factory surfaces and kitchen surfaces, and in animal feces, raw meats, raw poultry, frogs' legs, fish, shrimp and other seafood. *Salmonella* is the number one cause of food poisoning in the US register, with over two million cases per year. The bacterium *S. typhi*

causes typhoid fever in humans; other forms of salmonellosis produce milder symptoms. Such symptoms include diarrhea, mild fever, nausea, abdominal cramps, muscle pain, occasional vomiting and prostration. The onset of symptoms is typically 12–36 h after infection. Chickens and turkeys carry *Salmonella* in their intestines without any outward symptoms. Fortunately, thorough cooking kills them.

Recent developments in RMD: The conventional culture methods require 5–6 days for the detection of *Salmonella* from foods. Several rapid methods are currently available which require 24–48 h for their detection. Salmonella-Tek (Organon Teknika); Tecra Salmonella, Tecra Immunocapture, Automated Tecra OPUS and Tecra Unique (International Bioproducts-Tecra Diagnostics, PO Box 3489, Redmond, WA 98073, a division of Bioenterprises Pty Ltd, 28 Barcoo St., Roseville, NSW 2069, Australia); Locate Salmonella (Rhône-Poulenc); Assurance EIA (Biocontrol Systems, 19805 N. Creek Pkway, Bothell, WA 98011); Automated VIDAS (bioMérieux Vitek, 595 Anglum Dr., Hazelwood, MO 63042); Reveal (Neogen Corp.); Salmonella Screen/Verify (Vicom, L.P., 313 Pleasant St., Watertown, MA 02172); and BAX (DuPont). Most of these methods are based on enzyme linked immunosorbent assay (ELISA) technique.

According to the manufacturer, Idetek's (1245 Reamwood Ave., Sunnyvale, CA 94089) BIND rapid *Salmonella* test provides results in 22 h (which includes about 18 h for pre-enrichment) total test time. The test requires just four steps and less than 5 min hand-ons time per sample. Utilizing bacterial ice nucleation detection (BIND) technology, this system is highly specific and claimed to be simpler than ELISA or DNA hybridization. The system uses a genetically engineered virus to insert an ice nucleation gene into the bacteria. BIND induces *Salmonella* to produce a protein that causes solutions to freeze, resulting in a color change in the sample.

Direct Labeled Probe (DLP) assay (Gene-Trak, 94 South St., Hopkinton, MA 01748) utilizes nucleic acid hybridization technology for a fast and accurate detection of pathogens in food samples. This new DLP assay for *Salmonella* is claimed to reduce assay time to 90 min from about 2 h, after pre-enrichment.

Corporate addresses not provided here may be found in other sections of this chapter.

Objectives

This method describes an easy-to-use, 'Tecra-Salmonella Immunocapture System' as a screening procedure for the presence of *Salmonella* antigens. Immunocapture has been tested with more than 300 different strains of *Salmonella*. This system detects all serotypes of *Salmonella* with the exception of *S. pulorum* and *S. gallinarum*, which are considered to be poultry pathogens. This test is not confirmatory. All presumptive positive results must be confirmed using conventional culture methods.

Principle of the test

Detection of *Salmonella* uses an enzyme immunoassay employing highly purified antibodies prepared from antigens unique to *Salmonella*. Polyclonal antibodies to *Salmonella* antigen are adsorbed on to the internal surface of a 48- or 96-well microtiter tray. The enriched sample to be assayed is placed into the well of the tray. If *Salmonella* antigens are present in the sample, they will attach to specific antibodies adsorbed on the well. All other material in the samples is washed away.

The added conjugate (enzyme labeled antibodies specific for *Salmonella*) will bind to the *Salmonella* antigen–antibody complex adsorbed on the surface of the well. Wells are washed to remove unbound conjugate, and enzyme substrate is added. Dark blue–green color indicates the presence of *Salmonella* in the sample.

Materials and methods

Items supplied with the Tecra *Salmonella* Immunocapture System kit:

- (1) Wash concentrate (25 ml): Vial contains 2.90 g Tris, 14.06 g NaCl, 1.0 g Tween 20 and 0.003 g of thimerosal in water. Prepare working strength wash solution by diluting the contents of the vial to 2 liters with distilled water into a plastic squeeze bottle.
- (2) Control diluent: Vial contains 0.006 g Tris, 0.44 g NaCl, 0.0025 g Tween 20 and 0.005 g thimerosal in water.
- (3) Positive control (freeze-dried): Vial contains purified *Salmonella* antigen, which reacts with antibodies to *Salmonella*, 1 vial.

Prepare reconstituted positive control by transferring 3 ml control diluent to the vial of lyophilized positive control antigen; mix thoroughly. (Reconstituted control antigens are stable for 28 days when stored at 2–8°C.)

- (4) Negative control (freeze-dried lactose): This is nonreactive with *Salmonella* antibodies.

Prepare reconstituted negative control by transferring 2 ml control diluent to the vial of lyophilized negative control antigen; mix thoroughly. (Reconstituted control antigens are stable for 28 days when stored at 2–8°C.)

- (5) Conjugate diluent: Vial contains 0.42 g $\text{Na}_2\text{B}_4\text{O}_7$, 0.193 g NaCl, 0.22 g hydrolyzed gelatin and 0.0022 g thimerosal in water.
- (6) Conjugate (freeze-dried): Vial contains 147 ng anti-*Salmonella* antibodies (from sheep) conjugated to horseradish peroxidase, 0.0024 g CaCl_2 and 120 ng thimerosal. (Reconstituted conjugate is stable for 28 days when stored at 2–8°C.)

Prepare reconstituted conjugate by adding one set of conjugate diluent to the vial of lyophilized conjugate. Let the conjugate rehydrate at room temperature, mix, and then pour the contents of the vial into the conjugate diluent vial. Finally, gently mix the reconstituted conjugate.

- (7) Substrate diluent: Vial contains 0.116 g citric acid, 0.0011 g hydrogen peroxide and 0.0185 g of NaOH in water.
- (8) Substrate (freeze-dried): Vial contains 0.011 g 2,2'-azino-di(3-ethylbenz-thiazoline sulfonate) and 0.123 g NaH_2PO_4 .

Prepare reconstituted substrate by adding the vial of substrate diluent to the lyophilized substrate. Be sure the substrate has dissolved and the mixture is at room temperature prior to use. Reconstituted substrate will appear pale green. (Reconstituted substrate is stable for 28 days when stored at 2–8°C.)

- (9) Stop solution: Vial contains 0.15 g NaF in water. (Caution: Avoid contact with skin; if this occurs, wash the area with water.) Use this solution as received. No constitution is required.
- (10) Antibody-coated (Removawell) strips in resealable pouch: Polyclonal antibodies to *Salmonella*; wells. Store wells at 2–8°C when not used.
- (11) Removawell tray for securing wells or strips

- (12) Resealing strip
- (13) Package insert
- (14) Sample record sheets
- (15) Color card.

Other supplies:

- (1) M-broth: 5.0 g yeast extract; 12.5 g tryptone, 2.0 g D-mannose; 5.0 g Na citrate; 5.0 g NaCl; 5.0 g K_2HPO_4 ; 0.14 g $MnCl_2$; 0.8 g $MgSO_4$; 0.04 g $FeSO_4$; 0.75 g Tween 80. (All the ingredients are per liter of water.) Calculate the amount of M-broth required (2 ml/sample) and heat the solution to boiling for 1–2 min. Dispense 2 ml portions into screw-cap glass/plastic (not polyethylene) test tubes. Cap tubes loosely and autoclave for 15 min at 121°C. Tighten caps securely for storage. Final pH should be 7.0.
- (2) Modified buffered peptone water (MBPW): Peptone, 10 g; NaCl, 5 g; sodium phosphate, dibasic, 7.0 g; potassium phosphate, monobasic, 3.0 g. Rehydrate (total 20 g) in 1 liter distilled or deionized water. Dispense 225 ml in sterilizable bottles (number depending on the number of samples tested).
Dispense 4 ml aliquots into borosilicate glass test tubes (not polyethylene) for the assay and cap the test tubes. Sterilize in an autoclave for 15 min at 121°C.
- (3) Incubator: 35–37°C
- (4) Micropipettes (20–200 μ l)
- (5) Water bath
- (6) Plastic squeeze bottles (500 ml) for dispensing the wash solution
- (7) Plastic film wrap or sealable plastic container to cover wells during incubation.

General instructions

- Components of the kit must be refrigerated when not in use. The kit is intended for single use only. Do not reuse wells containing sample, reagents or wash solution.
- Include duplicate positive and negative control antigens with each group of test samples. All controls must function properly for the test to be valid.
- Use a date record sheet to identify the location of each test sample. Use separate pipettes for each sample and kit reagent to avoid cross-contamination.
- Components in the kit are intended for use as an integral unit. Do not mix components of different batch numbers.

Procedure

- (1) Pre-enrichment: Add 25 g of the sample to 225 ml of MBPW and thoroughly mix it in the media. If environmental samples are being used, add the swab and contents to the MBPW in a ratio of 1:10. Incubate the sample at 35–37°C overnight (for a minimum of 16 h).
- (2) Immunocapture:
 - (a) Take the previously prepared tubes of M-broth and MBPW, allowing one tube of M-broth and one of MBPW for each test sample. Label the M-broth tubes with the sample ID number and place the tubes in the 35–37°C incubator to prewarm.
 - (b) Cut open the pouch of the dipsticks and remove one dipstick for each sample to be tested. Replace the unused dipsticks in the pouch with the

silica gel and reseal by folding the opened end of the pouch and sliding the resealing strip over the folded end. Use the contents of each pouch within 2 months of opening.

- (c) Place the dipstick tubes into an appropriate rack, label with the sample ID number and unscrew the dipsticks, resting them back on the tubes. Add 70 μ l of buffer additive to each tube (provided in the kit).
 - (d) Transfer 1.8 ml of the pre-enriched (from step 1) sample to the appropriate dipstick tube. Replace the dipstick and tighten. Gently mix the contents. Incubate at room temperature (20–25°C) for a minimum of 20 min.
 - (e) At this stage, remove the MBPW and M-broth tubes from the incubator (from step 2a).
- (3) Wash the dipstick: Unscrew the dipstick and transfer it to the appropriately labeled tube of MBPW. Mix and wash the dipstick by inverting the tube twice.
 - (4) Replicate *Salmonella*:
 - (a) Transfer the dipstick to the corresponding M-broth tube. Snap the paddle from the dipstick stem by pressing firmly against the rim of the tube. The paddle should then be totally submerged in M-broth. Replace the cap on the tube and repeat the procedure for the remaining samples. Incubate the M-broth tubes containing the dipstick paddles at 35–37°C for a minimum of 5 h.
 - (b) Remove approximately 1 ml of the sample from each M-broth tube and transfer to appropriately labeled 5 ml tubes. Use new Pasteur pipettes each time. Refrigerate these tubes for confirmation of ELISA positive samples using standard plating procedures.
 - (5) Heat kill and release of *Salmonella*: Heat the remaining M-broth tubes containing the paddle in a boiling water bath for approximately 15 min to kill and release the bacteria. Cool to room temperature.
 - (6) Preparing the sample wells: Open the pouch and remove the required number of wells from the sealing film, allowing one well for each sample, one for the positive control and one for the negative control. Press the wells firmly into place in the holder provided. Replace unused wells in the foil pouch and reseal with the sealing strip.
 - (7) Addition of the samples:
 - (a) Using a new pipette tip for each sample, transfer 0.2 ml (200 μ l) of positive control, negative control and the heated M-broth sample solutions to individual wells as shown below:

+control	–control	sample 1	sample 2	sample 3...
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 - (b) Fill out the record sheet recording the sample positions. Cover the holder with plastic cling wrap film and incubate for 30 min at 35–37°C.
 - (8) Washing the wells:
 - (a) Emptying the wells: Ensure the wells are pressed securely in the holder. Quickly invert the holder and shake out the contents into a waste container.
 - (b) Remove residual liquid by striking the holder firmly several times face down on a thick pile of absorbent paper towels to effectively sample the residue.

- (c) Filling the wells with wash solution: Using a wide-nozzle squeeze bottle held above the plate, completely fill each well, taking care not to trap air-bubbles in the bottom of the wells.

WASH AND COMPLETELY EMPTY THE WELLS A TOTAL OF THREE TIMES AS DESCRIBED ABOVE.

- (9) Adding the conjugate: Add 0.2 ml of conjugate to each well. Cover the holder with plastic cling wrap film and incubate for 30 min at 35–37°C for adherence to the well surface.
- (10) Second, and subsequent washing: VERY IMPORTANT. Empty, then wash the wells a total of four times, using the sequence previously described in step 8.
- (11) Adding the substrate:
- (a) Add 0.2 ml of substrate to each well. Incubate at room temperature. Do not incubate tray next to an air conditioning unit or such place where the temperature may vary from the norm.
- (b) Color development tends to concentrate around the sides of the wells. Tap the holder gently to evenly distribute the color before reading the result.
- Incubate for a minimum of 10 min. Continue incubation until the color of the positive control well is equivalent to panel 4 on the color card supplied with the kit.
- (12) Adding the stop solution: Add 20 µl of stop solution to each well. Tap the sides of the holder gently to mix the contents.
- (13) Reading the results: Results can be read visually using the color card provided with the kit. Place the holder on a white background, then compare individual wells with the color card.

For the test to be valid

- The positive control must be at least as dark as panel 4 on the color card.
- The negative control must be within the negative range on the color card.
- A sample is considered NEGATIVE when the test has proven valid and the sample well has a color within the negative range on the color card.
- A sample is considered POSITIVE when the test has proven valid and the color in the sample well is greater than or equal to panel 3 on the color card.

If these criteria have not been met, consult the manufacturer's trouble-shooting guide, before repeating the test.

7.6.4 *Listeria monocytogenes*

Background

This is a Gram-positive, invasive type, motile psychrotrophic bacterium (capable of one doubling every 1.5 days at 4°C) that grows best at 35°C. It is quite hardy and resists the harmful effects of freezing, drying, salt and heat remarkably well. While lower temperatures enhance their survival, high temperature short time (HTST) pasteurization temperatures of 71.7°C for 15 s are not sufficient to kill them. *Listeria* infection has a high case-fatality rate, resulting in death or stillbirth in one third of all outbreak cases in susceptible individuals.

The bacterium is ubiquitous in nature, occurring in soil, vegetation and water. Plant cleanliness is crucial to control this organism. There are seven species recog-

nized in the genus *Listeria*: *L. monocytogenes*, *L. innocua*, *L. seeligeri*, *L. ivanovii*, *L. welshimeri*, *L. grayi* and *L. murrayi*. The last two species are reported to be non-pathogenic to humans.

Recent developments in RMD: The conventional methods of analysis for *Listeria* in food samples are complex and time consuming. The present FDA method requires a total time of 5–7 days. Rapid test kits that are currently available include Listeria-Tek (Organon-Teknika); UNIQUE-Listeria, Tecra-Listeria (International Bioproducts-Tecra Diagnostics, PO Box 3489, Redmond, WA 98073, a division of Bioenterprises Pty Ltd., 28 Barcoo St., Roseville, NSW 2069, Australia); Clearview (Unipath, 217 Colonnade Rd, Nepean, Ontario K2E 7K3, Canada); Automated VIDAS (bioMérieux); Assurance EIA (Bio Control Systems); Microgen's Listeria identification based on latex agglutination technology (Microgen Bioproducts Ltd, 1 Admiralty Way, Camberley, Surrey GU15 3DT, UK) and Listertest (Vicom). Microbiology International, Frederick, MD has recently announced the availability of ALOA 3-Way Selective Isolation Culture Medium with selective and enrichment supplements for the isolation of *Listeria* spp. and the presumptive identification of *L. monocytogenes* within 24 h. The company supplies prepared plates in 20-plate tubes and 120-plate cases. ALOA can be used according to the usual methods for the isolation of *Listeria* with direct streaking of the sample or after enrichment.

Corporate addresses not provided here may be found in other sections of this chapter.

Objectives

The present method employs a rapid Tecra visual immunoassay (VIA). It allows screening of samples for the presence or absence of all *Listeria* species after a shortened selective enrichment procedure.

This test does not confirm an absolute presence. The presumptive positive samples must be confirmed using the standard identification media and by performing the standard biochemical and serological tests.

Principle of the test

Detection of *Listeria* is based on enzyme immunoassay using highly purified antibodies prepared from antigen unique to *Listeria* spp. Polyclonal antibodies to *Listeria* antigens are adsorbed on to the internal surface of a 48/96-well microtiter tray. Samples to be assayed are placed into the wells of the tray. If *Listeria* antigens are present in the samples, they will attach to specific antibodies adsorbed on the well. All other material in the samples is washed away. The added conjugate (enzyme-labeled antibodies specific for *Listeria*) will bind to the *Listeria* antigen-antibody complex adsorbed on the surface of the well. Wells are washed to remove unbound conjugate and enzyme substrate is added. Dark blue-green color indicates the presumptive presence of *Listeria* in the sample.

Materials and methods

Items supplied with the kit include the following:

- (1) Wash concentrate (25 ml): Vial contains 1.45 g Tris, 7.03 NaCl, 0.5 g Tween 20 and 0.0025 g of thimerosal in water. Prepare working strength wash solution by diluting the contents of the vial to 2 liters with distilled water into a plastic squeeze bottle.

- (2) Control diluent: Vial contains 0.006 g Tris, 0.44 g NaCl, 0.0025 g Tween 20 and 0.005 g thimerosal in water.
- (3) Positive control (freeze-dried): Vial contains purified *Listeria* antigens which react with antibodies to *Listeria* spp. Prepare reconstituted positive control by transferring 3 ml control diluent to the vial of lyophilized positive control antigen and mix thoroughly. Reconstituted control antigens are stable for about 28 days when stored at 2–8°C.
- (4) Negative control (freeze-dried lactose): This is nonreactive with *Listeria* antibodies. The remaining control diluent (from step 3) will serve as the negative control.
- (5) Conjugate diluent (two/vials): Each vial contains 0.42 g $\text{Na}_2\text{B}_4\text{O}_7$, 0.193 g NaCl, 0.22 g hydrolyzed gelatin and 0.0022 g thimerosal in water.
- (6) Conjugate (freeze dried) (two/vials): Each vial contains 147 ng anti-*Listeria* antibodies (from sheep) conjugated to horseradish peroxidase, 0.0024 g calcium chloride and 120 ng thimerosal. Reconstituted conjugate is stable for about 28 days when stored at 2–8°C. Prepared reconstituted conjugate by adding one set of conjugate diluent to the vial of lyophilized conjugate. Let the conjugate rehydrate at room temperature, mix and then pour the contents of the vial into the conjugate diluent vial. Finally, gently mix the reconstituted conjugate.
- (7) Substrate diluent: Vial contains 0.116 g citric acid, 0.0011 g hydrogen peroxide and 0.0185 g of NaOH in water.
- (8) Substrate (freeze-dried): Vial contains 0.011 g 2,2'-azino-di(3-ethylbenzthiazoline sulfonate) and 0.123 g sodium di-hydrogen phosphate. Prepare reconstituted substrate by adding the vial of substrate diluent to the lyophilized substrate. Be sure the substrate has dissolved and the mixture is at room temperature prior to use. Reconstituted substrate will appear pale green (stable for about 28 days at 2–8°C).
- (9) Stop solution: Vial contains 0.15 g NaF in water. (Caution: Avoid contact with skin; if this occurs, wash the area with water.) Use this solution as received. No constitution is required.
- (10) Sample additive: Ready to use.
- (11) Antibody coated (Removawell) strips in resealable pouch: Polyclonal antibodies to *Listeria* spp.; wells. Store these wells at 2–8°C when not in use.
- (12) Removawell tray for securing wells or strips.
- (13) Resealing strip.
- (14) Package insert.
- (15) Sample record sheets.
- (16) Color card.

Other supplies:

- (1) University of Vermont (UVM) broth: Proteose peptone, 5.0 g; tryptone, 5.0 g; Lab Lemco powder (Oxoid), 5.0 g; yeast extract, 5.0 g; 20.0 g NaCl; 1.35 g KH_2PO_4 ; Na_2HPO_4 , 12.0 g; esculin, 1.0 g; nalidixic acid (2% sol. in 0.1 M NaOH), 1 ml. (All the ingredients are per liter of water.) The following filter-sterilized reagent should be added aseptically just before use:
Acriflavin hydrochloride (1.2% stock solution in distilled water), 1 ml/l.
(Use commercially available UVM broth, if possible.)

Calculate the amount of UVM-broth required (225 ml/sample) and heat the solution to boiling for 1–2 min. Dispense 225 ml portions into screw-cap glass/plastic (not polyethylene) bottles. Cap the tubes loosely and autoclave for 15 min at 121°C. Tighten caps securely for storage. Final pH should be 7.0.

- (2) Fraser broth: contains the following components in 1 liter of distilled water:

Protease petone, 5.0 g; tryptone, 5.0 g; Lab Lemco powder, 5.0 g; yeast extract, 5.0 g; NaCl, 20.0 g; KH_2PO_4 , 1.35 g; Na_2HPO_4 , 12.0 g; esculin, 1.0 g; lithium chloride, 3.0 g; nalidixic acid, 20 mg. Autoclave at 121°C for 15 min. Cool immediately after removal from the autoclave and dispense into 10 ml tubes.

Just before use the following filter-sterilized reagents should be added to each tube:

Acriflavin hydrochloride (2.5 mg/ml), 0.1 ml; ferric ammonium citrate (5% in distilled water), 0.1 ml. (Use commercially available Fraser broth, if available.)

Dispense 9.9 ml aliquots into plastic (not polyethylene) or borosilicate glass test tubes) for the assay and cap the test tubes. Sterilize in an autoclave for 15 min at 121°C.

- (3) Incubator: 35–37°C.
(4) Autopipettes (20–200 μl).
(5) Serological pipettes (1 ml).
(6) Water bath.
(7) Plastic squeeze bottles (500 ml) for dispensing the wash solution.
(8) Plastic film wrap or sealable plastic container to cover wells during incubation.

General instructions

- The expiry date on the outside of the box should be noted, and the kit used before this date.
- Components of the kit must be refrigerated when not in use. The kit is intended for single use only; do not reuse wells containing sample, reagents or wash solution.
- Include duplicate positive and negative control antigens with each group of test samples. All controls must function properly for the test to be valid.
- Use the data record sheet to identify the location of each test sample. Use separate pipettes for each sample and kit reagent to avoid cross-contamination.
- Reconstituted reagents have a two-month shelf life with the exception of the conjugate. Two bottles of conjugate are provided each with a reconstituted shelf life of one month.
- Components in the kit are intended for use as an integral unit. Do not mix components of different batch numbers.
- All components must be brought to *room temperature* before use.

Procedure

Pre-enrichment:

- (1) Add 25 g of the food sample to 225 ml of UVM broth in a blender or stomacher, and thoroughly mix the food sample in the media. Incubate the sample at 28–30°C for 22–24 h.
- (2) Transfer 0.1 ml of the above culture to 9.9 ml of Fraser broth and incubate for 22–24 h at 28–30°C.

Performing the immunoassay:

- (1) Sample heat treatment:
 - (a) Transfer 1 ml from the enrichment broth into a tube, and retain the remaining broth for confirmation of any positive ELISA results.
 - (b) Add 50 μ l (2 drops) of sample additive, mix, and heat for 15 min in a boiling water bath. Cool the heated sample to room temperature.
- (2) Preparing the sample wells: Cut open the pouch and remove the required number of wells from the sealing film, allowing one well for each sample, one for the positive control and one for the negative control. Press the wells firmly into the holder provided. Replace unused wells in the foil pouch and reseal with the sealing strip over the folded end. Use the contents of each pouch within 2 months of opening.
- (3) Addition of samples:
 - (a) Using a new pipette tip for each sample, transfer 0.2 ml (200 μ l) of positive control, negative control and the heated M-broth sample solutions to individual wells.

+control	-control	sample 1	sample 2	sample 3
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 - (b) Fill out the record sheet, recording the sample positions. Cover the holder with plastic cling wrap film and incubate for 30 min at 35–37°C.
- (4) Washing the wells:
 - (a) Emptying the wells: Ensure the wells are pressed securely in the holder. Quickly invert the holder and shake out the contents into a waste container.
 - (b) Remove residual liquid by striking the holder firmly several times face down on a thick pile of absorbent paper towels to effectively remove sample residue.
 - (c) Filling the wells with wash solution: Using a wide-nozzle squeeze bottle held above the plate, completely fill each well, taking care not to trap air-bubbles in the bottom of the wells.

WASH AND COMPLETELY EMPTY THE WELLS A TOTAL OF THREE TIMES AS OUTLINED ABOVE.
- (5) Adding the conjugate: Add 0.2 ml of conjugate to each well. Cover the holder with plastic cling wrap film and incubate for 30 min at 35–37°C for adherence to the well surface.
- (6) Second washing: VERY IMPORTANT. Empty, then wash the wells a total of *four* times, using the sequence previously described in step 4.
- (7) Adding the substrate:
 - (a) Add 0.2 ml of substrate to each well. Incubate at room temperature. Do not incubate the tray next to an air conditioning unit or such place where the temperatures may vary from the norm.
 - (b) Color development tends to concentrate around the sides of the wells. Tap the holder gently to evenly distribute the color before reading the result. Incubate for a minimum of 15 min. Continue the incubation until the color of the positive control well is equivalent to panel 4 on the color card.
- (8) Adding the stop solution: Add 20 μ l of stop solution to each well. Tap the sides of the holder gently to mix the contents.

- (9) Reading the results: Results can be read visually using the color card provided. Place the holder on a white background and compare individual wells with the color card.

For the test to be valid

- The positive control must be at least as dark as panel 4 on the color card.
- The negative control must be within the negative range on the color card.
- A sample is considered **NEGATIVE** when the test has proven valid and the sample well has a color within the negative range on the color card.
- A sample is considered **POSITIVE** when the test has proven valid and the color in the sample well is greater than or equal to panel 3 on the color card.

If these criteria have not been met, consult the manufacturer's trouble-shooting guide, before repeating the test.

7.6.5 *Staphylococcus aureus*

Background

Staphylococcus aureus is a spherical bacterium (coccus) which appears in pairs, short chains, or bunched, grape-like clusters. These organisms are Gram-stain positive. They are generally considered as mesophilic, with an optimum growth temperature of 37°C.

Some strains produce a highly heat-stable toxin that causes illness in humans. In fact, it causes one of the most commonly occurring types of food poisoning after ingesting the food containing preformed toxin in it.

The most common symptoms are nausea, vomiting, retching, abdominal cramping and prostration. The onset of symptoms is usually rapid, and recovery generally takes two days. A toxin dose of < 1.0 µg in contaminated food will produce symptoms of intoxication. This toxin level is achieved when *S. aureus* populations exceed 10⁵/g of sample.

Unique features:

- (1) No outward symptom of toxin (no odor) in the food.
- (2) Commonly found on humans (nose, hair and skin) and could find its way into food.
- (3) Large number of populations required for toxin production (see above).

The following procedure describes the conventional technique of enumerating *S. aureus* in food samples.

Recent development in RMD: Tecra visual immunoassay (VIA) is now available from International Bioproducts which provides a rapid, convenient, sensitive and specific screening test after selective enrichment. The actual procedure involves similar steps to those described above for *Salmonella* and *Listeria* visual immunoassays. Results are reported to be available within 24 h, and detection sensitivity is improved over conventional techniques.

Objectives

To enumerate and identify *S. aureus* using a direct plate count method.

Materials and methods

Sterile diluent (Butterfield's buffer or 0.1% peptone water)

Sterile blender

Glass beakers (250 ml)

70% alcohol

Sterile scissors and forceps

Dilution tubes with sterile diluent

Baird-Parker Agar Petriplates (BPA agar)

13 × 100 mm tubes with 0.3 ml sterile brain heart infusion broth (BHI broth)

Reconstituted coagulase plasma-EDTA

Bent glass rods

1 ml serological pipettes

Laminar flow hood

Incubator

Procedure

- (1) Prepare a 1 : 10 food homogenate (25 g food sample in 225 ml dilution buffer) in a sterile blender for exactly 1 min.
- (2) Make decimal dilutions and deliver 0.5 ml aliquots to duplicate BPA-agar plates.
- (3) Distribute inoculum over the surface of the plates with a sterile bent glass rod. When the inoculum is completely absorbed by the medium, invert the plates and incubate for 48 h at 35–37°C.
- (4) Select plates at the dilution having 20–200 well-isolated colonies.
- (5) Count the number of colonies in each of the following groups:
 - (a) Convex, shiny black, with or without a narrow gray–white margin, surrounded by a clear zone extending into the opaque medium.
 - (b) Convex, shiny black, with or without a narrow gray–white margin, surrounded by a clear zone extending into the opaque medium with an inner opaque zone.
 - (c) Convex, shiny black, with or without a narrow gray–white margin, with a diameter greater than or equal to 1 mm.
- (6) Select at least one colony from each group and inoculate each into separate tubes.
- (7) Add 0.5 ml reconstituted coagulase plasma containing EDTA to BHI-broth tubes and mix on a vortex mixer. Incubate in a water bath at 35–37°C and examine for clot formation at hourly intervals from 1 to 6 h.
- (8) Any degree of clot (more than a lump) formation is considered a positive coagulase reaction.
- (9) Consider all tubes giving a positive coagulase reaction in 6 h as *S. aureus*.
- (10) Calculate the total number of colonies (duplicate) represented by coagulase positive cultures and multiply by the appropriate sample dilution factor.
- (11) Record as the number of *S. aureus* per gram of sample.

8 The Future of HACCP in Controlling Seafood Safety

The global seafood catch seems to be stabilized. Many resources are fished beyond their maximum sustainable yields (MSY), in many cases due to overcapitalization in fishing gear and improvements in fish detection/catching techniques. The impact of global climatic changes on the future fishery resources is presently unknown. Internet buying, which is growing in small increments, will be another important factor in changing the seafood imports and exports throughout the world.

The industry's future depends on better production methods, maintaining environmental quality with stock production and stock enhancement programs, and working with countries throughout the world to protect the wild stocks that are currently present to prevent species extinction. Investing in aquaculture is a logical answer to supplement the fish captured in the wild and to ensure sustainable fisheries. Aquaculture industry has seen a tremendous growth in spite of its problems, related to pollution of the water and hazards from various chemicals and antibiotic residues in farm raised products. It may even contribute close to half of the world's fish and shellfish production by the next decade. Although this publication's focus was within the processing sector, it is essential that the HACCP principles be applied to the whole supply chain if food safety is to be assured.

The worldwide acceptance of a HACCP-based approach to food safety is not only due to governmental legislation but also partly due to market-driven pressures. While legislation is geared towards safety of the food, business interests are clearly related to production of quality foods and meeting the competition in supplying the product.

The US, Canada and the EC have implemented HACCP to cover the meat (USDA) and seafood (FDA) industry, and the US has recently proposed legislation for the fruit juice processing industry, but there is no federal legislation covering HACCP for the rest of the food, particularly the retail industry, which is left up to the state and local governments. There are also some differences in approach in North America and Europe to meet their respective governments' legislation. However, the one similarity is that all importing countries have to meet the same standard as the domestic producers.

While Australia and New Zealand have passed partial HACCP legislation, other countries in the region are forced to accept HACCP to meet the market demands of importers. In Australia there are legislated HACCP requirements for the meat and dairy industries and all exported food products. All the fishing vessels that process seafood for export need Food Production Accreditation (FPA), a HACCP-based system administered by the Australian Quarantine Inspection Service (AQIS) which is similar in function to that of the USFDA. However, domestic regulations have no connection to requirements for imports. Parallel developments by the major super-market chains in Australia and the UK have meant that most food producers and

processors have voluntarily implemented HACCP-based Quality Assurance Systems by demanding compliance from their suppliers. There was proposed federal legislation in Australia covering the domestic food industry, but this approach seems to have been abandoned for now in favor of each of the seven states and territories implementing their own food safety legislation.

In an export-focused country like New Zealand, all areas of the food industry have implemented HACCP to meet their trading partners' requirements, in order to enable their industry to keep an edge on their trading partners. Parts of Asia such as Japan are using third country standards as their defacto standards (Ropkins and Beck, 2000).

The other factors in favor of HACCP are food safety concerns, support from domestic industries of various countries, and ongoing efforts by concerned international bodies such as the EU and the Food and Agriculture Organization (FAO) to harmonize individual country inspection systems and requirements. The recommendations of the Codex Committee on Food Hygiene encourage the international use of the HACCP system. We can expect to see suppliers providing a much greater share of the market in the US, the EU, Japan and other developed countries, especially with value-added products such as breaded fish and shrimp.

In future, one can see the potential of extending the application of a HACCP-based approach to food caterers and retailers to produce safe food for the consumer.

References

- Agriculture Canada (1992) *Food Safety Enhancement Program (FSEP), Implementation Manuals*, Volumes I, II and III.
- ANSI/NSF (1992) *Air Curtains for Entrance Ways in Food and Food Service Establishments*, 37–1992.
- AOAC Official Methods of Analysis (1990) *Association of Official Analytical Chemists, 15th Edition, Volumes 1 & 2*, Arlington, VA.
- CFR (1970) Code of Federal Regulations, Title 29: Parts 1900–1999. *Occupational Safety and Health Act*.
- CFR (1981) Code of Federal Regulations, Title 21: Part 110. *Current Good Manufacturing Practice (Sanitation) in Manufacturing, Processing, Packing or Holding Human Food*. 42 FR 14338, 15 March 1977, as amended at 46 FR 8459, 27 January 1981.
- CFR (1994) Code of Federal Regulations, Title 21: Parts 123 and 1240. *Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products*. 28 January 1994. Department of Health and Human Services, Food and Drug Administration, 21 CFR Parts 123 and 1240. *Federal Register* 59:19.
- CFR (1995) Code of Federal Regulations, Title 21: Parts 123 and 1240. *Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule*, 18 December 1995. Department of Health and Human Services, Food and Drug Administration, *Federal Register* 60:242:65096–5202.
- CFR (1997) Code of Federal Regulations. Title 21, Volume 2, Parts 100 to 169 revised as of 1 April 1997. *Food and Drugs*. Department of Health and Human Services, Food and Drug Administration, *Federal Register* 61 FR 42761.
- Codex Committee on Food Hygiene (1993) Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System. In *Training Considerations for the Application of the HACCP System to Food Processing and Manufacturing*, WHO/FNU/FOS/93.3 II, World Health Organization, Geneva.
- Codes Committee on Food Hygiene (1977) HACCP System and Guidelines for its application, Annex to CAC/RCP 1-1969. Rev.3. In *codex Alimentarius Food Hygiene Basic Texts, Food and Agriculture Organization of the United Nations*, WHO, Rome.
- Cooper, M., B. Deyell and E. Jenkins (1997) Western College of Veterinary Medicine, Saskatoon, Saskatchewan, Canada. (duke.usask.ca/~misra/virology/aquacul/general.html)
- FAO (1998) *The State of World Fisheries and Aquaculture (SOFIA)*, FAO, Rome, Italy.
- FAO (2000) Globefish database. (www.fao.org)
- FAO/WHO (1998) Joint Codex Alimentarius Commission, Food and Agriculture Organization, *Report of the Twenty-third session of the Codex Committee on Fish and Fishery Products*, Bergen, Norway, June 8–12.
- FDA (1938) The Federal Food, Drug, and Cosmetics Act, 21 U.S.C. 321 to 394. Department of Health and Human Services, Food and Drug Administration, Washington, DC.
- FDA (1966) Fair Packaging and Labeling Act, 15 U.S.C. 1451 to 1461 as amended by Public Law 102–329. Department of Health and Human Services, Food and Drug Administration, Washington, DC.
- FDA (1998) Fish and Fishery Products Hazards and Controls Guide, Center for Food Safety and Applied Nutrition, Department of Health and Human Services, Food and Drug Administration, Washington, DC.

- GATT (1991) Draft Final Act Embodying the *Results of the Uruguay Round of Multilateral Trade Negotiations*, 20 December 1991.
- Hardy, R.W. (1991) 'Application of HACCP Principles in Feed Manufacture', in the *Proceedings of Aquaculture Feed Processing and Nutrition Workshop, Thailand and Indonesia, 19–25 September*. American Soybean Association, Singapore.
- ISO (1998a) *Selection and Use of ISO 9000*. International Organization for Standardization, Geneva, Switzerland. (www.iso.ch)
- ISO (1998b) *Selection and Use of ISO 14000 – Meet the Whole Family*, International Organization for Standardization, Geneva, Switzerland.
- ISO Bulletin (1999) *Summary of the Year 2000 Revisions on ISO Good Quality Management System Standards*, May 1999.
- Kanduri, L. and M. Hudak-Roos (1993a) *HACCP and Quality Assurance Programs – Student Manual*, NOAA Award No. NA26FK0400–01, Kingsborough Community College of The City University of New York, Brooklyn, NY.
- Kanduri, L. and M. Hudak-Roos (1993b) *HACCP and Quality Assurance Programs – Teacher Manual*, NOAA Award No. NA26FK0400–01, Kingsborough Community College of The City University of New York, Brooklyn, NY.
- Kanduri, L. and M. Hudak-Roos (1993c) *HACCP and Quality Assurance Programs – Laboratory Manual*, NOAA Award No. NA26FK0400–01, Kingsborough Community College, Brooklyn, NY.
- Morris, C.E. (1999) Sanitation system eases SSOPs. *Food Engineering* 71(3): 75.
- NACMCF (1997) National Advisory Committee on Microbiological Criteria for Foods, Adopted 14 August 1997, 'Hazard Analysis and Critical Control Points Principles and Application Guidelines.'
- National Seafood HACCP Alliance (1998) *HACCP: Hazards Analysis Critical Control Point Training Curriculum, 2nd edn*. Publication UNC-SG-96-02, North Carolina Sea Grant, Raleigh (North Carolina State University).
- National Seafood HACCP Alliance (1999) 'The Compendium of Fish and Fishery Product Processing Methods, Hazards and Controls', Robert J. Price, Extension Specialist, Seafood Products, Food Science and Technology, University of California, Davis, CA 95616-8598.
- Ropkins, K. and A.J. Beck (2000) 'Evaluation of worldwide approaches to the use of HACCP to control food safety', *Trends in Food Science and Technology*, 11: 10–21.
- USCS (1930) United States Customs Service, Tariff Act of 1930 as amended by the Tariff Classification Act of 1962. 19 U.S.C. 1202–1527, 46 Stat 741 and 76 Stat 73–74.
- USDA (1980) United States Department of Agriculture, National Aquaculture Act, Public Law 96–362, 94 Stat 1198, 16 U.S.C. 2801, *et seq.*
- USDA (1995) United States Department of Agriculture, Food Safety and Inspection Service, '9 CFR Parts 308, 318, 320, 325, 326, 327, and 381: *Pathogen Reduction; HACCP Systems; Proposed Rule*', 60 FR 6774, No. 23, 3 February 1995.
- USDA (1996) List of Proprietary Substances and Nonfood Compounds Authorized for Use Under USDA Inspection and Grading Programs.
- USDL (1970) United States Department of Labor, Public Law 91–596, 20 December 1970 as amended by Public Law 105–241, 29 September 1998.

FURTHER READING

General

- Ahmed, F.E. (ed.) (1991) *Seafood Safety*, Committee on Evaluation of the Safety of Fishery Products, Food and Nutrition Board, Institute of Medicine, NAS, National Academy Press.

- Brown, R. and R. Palmatees (1976) *Seafood Plant Design*. Pub. No. 04-5-158-48. Washington Seagrant Program, University of Washington, Seattle, WA.
- FDA (1999) *Food Code*, US Department of Health and Human Services, Public Health Service, Food and Drug Administration.
- Finley, J.W. and D.E. Schwass (eds) (1983) *Xenobiotics in Foods and Feeds*, American Chemical Society, Washington, DC.
- Gorga, C. and L.J. Ronsivalli (1998) *Quality Assurance of Seafood*, Van Nostrand Reinhold, New York.
- Guthrie, R.K. (1980) *Sanitation in Food Production and Processing*, AVI Publishing Co., Westport, CT.
- Huss, H.H. (1994) 'Assurance of Seafood Quality', *FAO Fisheries Technical Paper 334*, Food and Agriculture Organization of the United Nations, Rome.
- ICMSF (1986) 'International Committee on Microbiological Specifications for Foods', *Sampling for Microbiological Analysis: Principles and Specific Applications, Microorganisms in Foods*, Vol. 2, 2nd edn, University of Toronto Press, Toronto.
- Lamprecht, J.W. (1992) *ISO 9000: Preparing for Registration*, ASQC Quality Press, Marcel Dekker, New York.
- Lawson, T.B. (1995) *Fundamentals of Aquacultural Engineering*, Chapman and Hall, an ITP Company, New York.
- Marriott, N.G. (1985) *Principles of Sanitation*, The AVI Publishing Company, Westport, CT.
- Minneapolis Grain Exchange Weekly Fax Report, Michelle Carlson and Peggy Berg, Minneapolis Grain Exchange, 400 South 4th Street, Suite 130, Minneapolis, MN. (www.mgex.com)
- NAS (1985) Subcommittee on Microbiological Criteria, Committee on Food Protection, Food and Nutrition Board, National Research Council, *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*, National Academy Press.
- WHO (1987) International Committee on Microbiological Specifications for Foods. 'Prevention and control of food-borne salmonellosis through the application of HACCP system', World Health Organization, Geneva.

HACCP-related

- Bauman, H.E. (1992) 'Introduction to HACCP', in *HACCP: Principles and Applications*, Van Nostrand Reinhold, New York.
- Corlette, D.A. (1998) *HACCP User's Manual*. Aspen Publishers, Gaithersburg, MD.
- Debevere, J. and K. Neyts (1998) 'Application of HACCP in processing raw tropical shrimp', *Infofish International*, 3/98.
- Kanduri, L. and M. Hudak-Roos (1993) 'HACCP in a College Curriculum', *paper presented at the Third Joint Conference of The Atlantic Fisheries Technology Society and Tropical and Sub-Tropical Fisheries Technology Society*, 29 August–1 September 1993 at Williamsburg, VA.
- Lee, J.S. and K.S. Hildebrand, Jr (1992) 'Hazard Analysis and Critical Control Point Applications to the Seafood Industry', ORESU-H-92-001, Oregon Sea Grant, Oregon State University, Corvallis, OR.
- Mortimore, S.E. and C.A. Wallace (1998) *HACCP A Practical Approach*, 2nd edn, Aspen Publishers, Gaithersburg, MD.
- NFPA (1993) Microbiology and Food Safety Committee of the National Food Processors Association 'HACCP Implementation: A Generic Model for Chilled Foods', *Journal of Food Protection*, 56(12): 1077–84.
- NMFS (1989) 'HACCP Regulatory Model: Raw Shrimp', *Model Seafood Surveillance Project*, National Marine Fisheries Service, Office of Technology and Information Service, National Seafood Inspection Laboratory, Pascagoula, MS.

- NMFS (1989) 'HACCP Regulatory Model: Cooked Shrimp', *Model Seafood Surveillance Project*, National Marine Fisheries Service, Office of Technology and Information Service, National Seafood Inspection Laboratory, Pascagoula, MS.
- NMFS (1989) 'HACCP Regulatory Model: Breaded Shrimp', *Model Seafood Surveillance Project*, National Marine Fisheries Service, Office of Technology and Information Service, National Seafood Inspection Laboratory, Pascagoula, MS.
- Pierson, M.D. *et al.* (1992) *HACCP: Principles and Applications*, Van Nostrand Reinhold, New York.

Aquaculture

- Doré, I. (1987) *An Illustrated Guide to Shrimps of the World*, Osprey Books, New York.
- Doré, I. (1993) *Shrimp Supply, Products and Marketing in the Aquaculture Age*, Urner Barry Publications, Toms River, NJ.
- Frimodt, C. and I. Doré (1987) *An Illustrated Guide to Shrimps of the World*, Urner Barry Publications, Toms River, NJ.

Regulations

- CFR. *Title 21, Volume 1, Parts 1 through 99*, General Regulations, Enforcement Policy, Administrative Functions, Public Hearings, Disclosure of FDA Records, Bio-research, Color Additives.
- CFR. *Title 21, Volume 2, Parts 100 through 169*, Food Labeling, Food Standards, Special Dietary Foods, Good Manufacturing Practices for Foods, Thermally Processed Low-acid Foods, Acidified Foods (human food).
- CFR. *Title 21, Volume 3, Parts 170 through 199*, Food Additives, Seafood Inspection Program (human food).
- CFR. *Title 21, Volume 6, Parts 500 through 599*, Animal Food Labeling, Animal Drugs, Feeds, and Related Products.
- EU (1991) The Council of the European Communities, Council Directive of 22 July 1991. 'Laying Down the Health Conditions for the Production and Placing on the Market of Fishery Products', *Official Journal of the European Communities*, No. L 268/15.
- EU (1993) Council Directive 93/43/EEC (14 June) on the Hygiene of Foodstuffs, *Official Journal of the European Communities*, July 19, 1993, No. L175/I.
- FDA (1995) Addendum to the FDA European Union Health Certificate Program Protocol of June, 1993. December 5 1995. Office of Seafood, Department of Health and Human Services, Food and Drug Administration.
- FAO/WHO (1976) Codex Alimentarius Commission, Food and Agriculture Organization, *Recommended International Code of Practice for Fresh Fish*, 2nd edn.
- Federal Standard (1977) *Sanitation Standards for Fish Plants*, FED-STD-369, Academy of Health Sciences, US Army, Fort Sam Houston, Houston, TX.

Testing

- Cheuk, W.L. and G. Finne (1981) 'Decomposition (Chemical Indices): Modified Colorimetric Method for Determining Indole in Shrimp', *Journal of the Association of Analytical Chemists* 64: (4): 783–85.
- FDA (1983) 'Inspection Methods: Shrimp', *FDA Inspection Operations Manual*, Sub chapter 616, 25 July 1983.
- FDA (1984) *Bacteriological Analytical Manual (BAM)*, 6th edn, Food and Drug Administration, Washington, DC.
- NMFS (1993) *National Marine Fisheries Service Fishery Products Inspection Manual*, Part 1, Chapter 9, Section 02, 20 October 1993.

Appendices

- 1 Forms for Evaluating Prerequisite Programs
- 2 Example of a Daily Sanitation Report
- 3 An Illustrated Example of a HACCP Plan – Processing Cooked Shrimp
- 4 Example of Detailed Product Specifications for Fresh and Frozen Green Headless and PUD Shrimp
- 5 Raw Material Evaluation Worksheet
- 6 HACCP Regulations
- 7 Abbreviations Used in This Book
- 8 Recommendations for Factory Vessels
- 9 Celsius–Fahrenheit Temperature Conversions
- 10 Conversion Factors

Appendix 1

Forms for Evaluating Prerequisite Programs*

(See Chapter 2)

Name of the Company:
 Address:
 Product:
 Signature:
 Date:

Assessment criteria	Check if complete	Comments/actions to address incomplete programs
(A) Premises		
1 Building exterior		
1.1 Outside property and building		
• Building facility not located in close proximity to any environmental contaminants	☐	
• Roadways properly graded, compacted, dust proofed and drained	☐	
• Surroundings adequately drained	☐	
• Building exterior designed, constructed and maintained to prevent entry of contaminants and pests, e.g. no unprotected openings, air intakes are appropriately located, and the roof, walls and foundation are maintained to prevent leakage	☐	
2 Building interior		
2.1 Design, construction and maintenance		
• Facilities adequate for maximum production volume	☐	
• Floors, walls, ceilings constructed of material that is durable, impervious, smooth, cleanable, and suitable for the production conditions in the area	☐	
<i>continued</i>		

*These forms are modified from Agriculture Canada, Food Safety Enhancement Program Implementation Manuals (1992).

Assessment criteria	Check if complete	Comments/actions to address incomplete programs
steam, condensation or dust and to remove contaminated air		
• Ventilation openings are equipped with close-fitting screens or filters to prevent the intake of contaminated air. Filters are cleaned or replaced as appropriate	☐	
• In microbiologically sensitive areas positive air pressure is maintained	☐	
2.4 Waste disposal		
• Drainage and sewage systems are equipped with appropriate traps and vents	☐	
• Establishments are designed and constructed so that there is no cross-connection between the sewage system and any other waste effluent system in the establishment	☐	
• Effluent or sewage lines do not pass directly over or through production areas unless they are controlled to prevent contamination	☐	
• Adequate facilities and equipment are provided and maintained for the storage of waste and inedible material prior to removal from the establishment. These facilities are designed to prevent contamination	☐	
• Containers used for waste are clearly identified, leakproof, and where appropriate are covered	☐	
• Waste is removed and containers are cleaned and sanitized at an appropriate frequency to minimize contamination potentials	☐	
3 Sanitary facilities		
3.1 Employee facilities		
• Where appropriate, handwashing stations are operated hands free and sanitizer hand dips are available	☐	
• Washrooms have hot and cold potable running water, soap dispensers, soap, sanitary hand drying equipment or supplies and a cleanable waste receptacle	☐	
• Washrooms, lunchrooms and changing rooms are provided with adequate floor drainage and ventilation and are maintained in a manner to prevent contamination	☐	
• Handwashing notices are posted in appropriate areas	☐	

continued

Assessment criteria	Check if complete	Comments/actions to address incomplete programs
Toilets are separated from and do not open directly into food processing areas	☐	
3.2 Equipment cleaning and sanitizing facilities		
Facilities are constructed of corrosion-resistant materials capable of being easily cleaned, and are provided with potable water at temperatures appropriate for the cleaning chemicals used	☐	
Equipment cleaning and sanitizing facilities are adequately separated from food storage, processing and packaging areas to prevent contamination	☐	
4 Water/steam/ice quality and supply		
4.1 Water and ice		
Water meets the requirements of the concerned health authority	☐	
Water is analyzed by the manufacturer or municipality at a frequency adequate to confirm its potability. Water from sources other than municipal supplies must be treated as necessary and tested to ensure potability	☐	
There are no cross-connections between potable and nonpotable water supplies	☐	
All hoses, taps or other similar sources of possible contamination are designed to prevent back-flow or back-siphonage	☐	
The volume, temperature and pressure of the potable water are adequate for all operational and clean-up demands	☐	
Water treatment chemicals, where used, are listed in the 'Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products', published by Agriculture and Agri-Food Canada or the manufacturer has a 'letter of no objection' from Health Canada	☐	
The chemical treatment is monitored and controlled to deliver the desired concentration and to prevent contamination	☐	
Recirculated water is treated, monitored and maintained as appropriate for the intended purpose	☐	
Recirculated water has a separate distribution system which is clearly identified	☐	
Ice used as an ingredient or in direct contact with food is made from potable water and is protected from contamination	☐	

continued)

Assessment criteria	Check if complete	Comments/actions to address incomplete programs
4.2 Steam		
Boiler treatment chemicals used are listed in the 'Reference Listing of Accepted Construction Materials, Packaging Materials, and Non-Food Chemical Products' or the manufacturer has a 'letter of no objection' from the concerned health authority	☐	
Boiler feed water is tested regularly and the chemical treatment is controlled to prevent contamination	☐	
The steam supply is generated from potable water and is adequate to meet operational requirements	☐	
4.3 Records		
- The manufacturer has records available to demonstrate the adequacy of the microbiological and/or chemical safety of the water and steam supply as follows: - Water/Ice Potability Records (water source, sample site, analytical results, analyst and date) - Water Treatment Records (method of treatment, sample site, analytical results, analyst and date) - Boiler Feedwater Treatment Records (method of treatment, analytical results, analyst and date)	☐	
(B) Transportation and storage		
1 Transportation		
1.1 Food carriers		
- The manufacturer verifies that carriers are suitable for the transportation of food. For example: - Carriers are inspected by the manufacturer on receipt and prior to loading to ensure they are free from contamination and suitable for the transportation of food, and/or - The manufacturer has a program in place to demonstrate the adequacy of cleaning and sanitizing, e.g. for bulk carriers a written cleaning and sanitizing procedure is available, and/or - Where the same carriers are used for food and nonfood loads (e.g. dual use), procedures are in place to restrict the type of nonfood loads to those that do not pose a risk to subsequent food loads after an acceptable clean-out or to food	☐	

continued

Assessment criteria	Check if complete	Comments/actions to address incomplete programs
loads in the same shipment, e.g. the manufacturer receives a cleaning certificate and a record of the previous material transported prior to loading or unloading dual use tankers		
• The manufacturer has a program in place to verify the adequacy of cleaning, e.g. tanker inspections, sensory evaluation of ingredients and/or analysis as appropriate	☐	
• Carriers are loaded, arranged and unloaded in a manner that prevents damage and contamination of the food and packaging materials	☐	
• Incoming materials (food, nonfood, packaging) are received in an area separate from the processing area	☐	
• Bulk tanks are designed and constructed to permit complete drainage and to prevent contamination	☐	
• Where appropriate, materials used in carrier construction are suitable for food contact	☐	
1.2 Temperature control		
• Ingredients requiring refrigeration are transported at 4°C or less and are appropriately monitored. Frozen ingredients are transported at temperatures that do not permit thawing	☐	
• Finished product is transported under conditions to prevent microbiological, physical and chemical deterioration	☐	
2 Storage		
2.1 Incoming material storage		
• Ingredients requiring refrigeration are stored at 4°C or less and are appropriately monitored. Frozen ingredients are stored at temperatures that do not permit thawing	☐	
• Ingredients and packaging materials are handled and stored in a manner to prevent damage and/or contamination	☐	
• Ingredient and where appropriate packaging material rotation is controlled to prevent deterioration and spoilage	☐	
• Humidity sensitive ingredients and packaging materials are stored under appropriate conditions to prevent deterioration	☐	

continued

Assessment criteria	Check if complete	Comments/actions to address incomplete programs
2.2 Nonfood chemicals receiving and storage		
• Chemicals are received and stored in a dry, well-ventilated area	☐	
• Nonfood chemicals are stored in designated areas such that there is no possibility for cross-contamination of food or food contact surfaces	☐	
• Where required for ongoing use in food handling areas these chemicals are stored in a manner that prevents contamination of food, food contact surfaces or packaging materials	☐	
• Chemicals are stored and mixed in clean, correctly labeled containers	☐	
• Chemicals are dispensed and handled only by authorized and properly trained personnel	☐	
2.3 Finished product storage		
• Finished product is stored and handled under conditions to prevent deterioration	☐	
• Stock rotation is controlled to prevent deterioration that could present a health hazard	☐	
• Returned defective or suspect product is clearly identified and isolated in a designated area for appropriate disposition	☐	
• Finished product is stored and handled in a manner to prevent damage, e.g. control of stacking heights and forklift damage	☐	
(C) Equipment		
1 General equipment		
1.1 Design and installation		
• Equipment is designed, constructed and installed to ensure that it is capable of delivering the requirements of the process	☐	
• Equipment is designed, constructed and installed to be accessible for cleaning, sanitizing, maintenance and inspection	☐	
• Equipment is designed, constructed, and installed to prevent contamination of the product during operations, e.g. location of lubricant reservoirs	☐	
• Where necessary, equipment is exhausted to the outside to prevent excessive condensation	☐	
• Equipment is designed, constructed and installed to permit proper drainage and where appropriate, is connected directly to drains	☐	

continued

Assessment criteria	Check if complete	Comments/actions to address incomplete programs
equipment maintenance activity, date, person and reason for activity		
1.5 Calibration records		
Information expected in calibration records includes identification of equipment, date, person responsible and calibration results	☐	
(D) Personnel		
1 Training		
1.1 General food hygiene training		
The manufacturer has a written training program for employees	☐	
Appropriate training in personal hygiene and hygienic handling of food is provided to all food handlers at the beginning of their employment	☐	
The original food hygiene training is reinforced and updated at appropriate intervals	☐	
Training is appropriate for the complexity of the manufacturing process and the tasks assigned, e.g. personnel are trained to understand the importance of the critical control points for which they are responsible, the critical limits, the procedures for monitoring, the action to be taken if the limits are not met, and the records to be kept	☐	
Personnel responsible for maintenance of equipment impacting on food safety have been appropriately trained to identify deficiencies that could affect product safety and to take the appropriate corrective action, i.e. in-house repairs, contract repairs	☐	
Individuals performing maintenance on specific equipment are appropriately trained, e.g. closing machines, recorders, dudding equipment	☐	
Personnel and supervisors responsible for the sanitation program are appropriately trained to understand the principles and methods required for effective cleaning and sanitizing	☐	
Additional training is provided as necessary to ensure current knowledge of equipment and process technology, e.g. specific technical training, apprenticeship programs	☐	

continued

Assessment criteria	Check if complete	Comments/actions to address incomplete programs
2 Hygiene and health requirements		
2.1 Cleanliness and conduct		
• All persons wash their hands upon entering food handling areas, before starting work, after handling contaminated materials, after breaks, and after using toilet facilities	☐	
• Where necessary to minimize microbiological contamination, employees use disinfectant hand dips	☐	
• Protective clothing, hair covering, footwear and/or gloves, appropriate to the operation that the employee is engaged in, are worn and maintained in a sanitary manner, e.g. employees in production areas wear effective hair coverings	☐	
• Any behavior which could result in contamination of food, such as eating, use of tobacco, chewing gum, or unhygienic practices such as spitting are prohibited in food handling areas	☐	
• All persons entering food handling areas remove jewelry and other objects which may fall into or otherwise contaminate food. Jewelry, including wedding bands and medical alerts which cannot be removed, are covered	☐	
• Personal effects and street clothing are not kept in food handling areas and are stored in a manner to prevent contamination	☐	
• Access of personnel and visitors is controlled to prevent contamination. The traffic pattern of employees prevents cross-contamination of the product	☐	
2.2 Communicable diseases/injuries		
• The manufacturer has and enforces a policy to prevent personnel known to be suffering from, or known to be carriers of a disease transmissible through food, from working in food handling areas	☐	
• The manufacturer requires that employees advise management when they are suffering from a communicable disease likely to be transmitted through food	☐	
• Employees having open cuts or wounds do not handle food or food contact surfaces unless the injury is completely protected by a secure waterproof covering, e.g. rubber gloves	☐	

continued

Assessment criteria	Check if complete	Comments/actions to address incomplete programs
(E) Sanitation and pest control		
1 Sanitation		
1.1 Sanitation program		
The manufacturer has a written cleaning and sanitation program for all equipment which includes: the name of responsible person, the frequency of the activity, chemicals and concentration used, temperature requirements, procedures for cleaning and sanitizing as follows:	☐	
<i>For Cleaned out of Place Equipment (COP)</i> <i>e.g. hand-cleaned</i> - identify equipment and utensils - disassembly/reassembly instructions as required for cleaning and inspection - areas on equipment requiring special attention are identified - method of cleaning, sanitizing and rinsing	☐ ☐ ☐ ☐	
<i>For Cleaned in Place Equipment (CIP)</i> - identify lines and/or equipment - CIP set-up instructions - method of cleaning, sanitizing and rinsing	☐ ☐ ☐	
- Disassembly/reassembly instructions as required for cleaning and inspection - The manufacturer has a written cleaning and sanitation program for premises, production and storage areas, which specifies areas to be cleaned, method of cleaning, person responsible and the frequency of the activity. Special sanitation and housekeeping procedures required during production are specified within the document, e.g. removal of product residues during breaks - Cleaning and sanitizing equipment is designed for its intended use and is properly maintained - Chemicals are used in accordance with the manufacturer's instructions and are listed in the 'Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Agents' or the manufacturer has a 'letter of no objection' from the concerned health authority - The sanitation program is carried out in a manner that does not contaminate food or packaging materials during or subsequent to cleaning and sanitizing, e.g. aerosols, chemical residues - Effectiveness of the sanitation program is monitored and verified (e.g. by routine	☐ ☐ ☐ ☐ ☐ ☐	

continued

Assessment criteria	Check if complete	Comments/actions to address incomplete programs
(F) Recalls		
1 Recall system		
1.1 Procedure		
• The written procedure includes:	☐	
• The person or persons responsible, e.g. recall coordinator(s)	☐	
• The roles and responsibilities for coordination and implementation of a recall	☐	
• Methods to identify, locate and control recalled product	☐	
• A requirement to investigate other products that may be affected by the hazard and that should be included in the recall	☐	
• Procedure for monitoring the effectiveness of the recall, e.g. effectiveness check to the appropriate level of distribution specified in the recall notice	☐	
• Immediate notification of the Director, Health Protection Branch, in the region where the manufacturer is located. In some cases this may be through the regulatory agency having jurisdiction. This notification includes the following:	☐	
• amount of product produced, in inventory, and distributed	☐	
• name, size, code or lot numbers of food recalled	☐	
• area of distribution of product, e.g. local, national, international	☐	
• reason for the recall	☐	
1.2 Product code identification (where mandatory)		
• Each prepackaged food has permanent, legible code marks or lot numbers on the packages	☐	
• The code identifies the establishment, the day, month and year in which the food was produced	☐	
• Code marks used and the exact meaning of the code are available	☐	
1.3 Recall capability		
• The manufacturer is capable of producing accurate information on a timely basis to verify that all affected product can be rapidly identified and removed from the marketplace	☐	

continued

Appendix 2

Example of a Daily Sanitation Report*

Instructions

1. Place initials by each item OKAYED (meets SSOP standard) by inspection OR observation
2. Date and sign the form
3. Return form to the Plant Manager
4. Keep form on file for 2 years

Condition(s)/ Procedure(s)	–	Date	Time ☺	Sanitizer Conc.	Equipment condition/ Corrective Actions	Initial
-------------------------------	---	------	-----------	--------------------	--	---------

Plant water is from the municipal supply (public water system)

Preoperational (startup) sanitation

Food contact surfaces and utensils						
Toilets, employee rest rooms						
Cleaning agents/ sanitizers/paper towels						
Walls, floor, ceilings						
Refrigerator						
Freezer						
Toxic compounds identified and stored properly						
Pest control (see Pest control log)						

*This is adapted from a generic SSOP developed by Dr Robert Price, University of California Davis under a grant from NOAA and National Sea Grant College Program, Department of Commerce, Grant number NA36RG0537, Project number A/EA-1 through the California Sea Grant Program, and in part by the California State Resources Agency.

Operational sanitation (every 4 hours during daily operations)

Gloves/garments						
Knives						
Cutting boards						
Hand sanitizer strength						
Brining/thaw tubs						
Band saw						
Slicer						
Vacuum packing machine						
Smoke house						
Cutting tables						
Trolleys/hooks						
Waste receptacles						

Similar check lists may be developed for aquaculture ponds/recirculating tanks used in the hatchery/grow-out areas specific to the situation.

Chemicals approved for use

Sodium hypochlorite sanitizer brand:

Usage: Sanitation rinse 100 PPM – Thaw tanks 30 PPM

Quaternary ammonium sanitizer brand:

Usage: Food contact surfaces, floors 200 ppm – Disinfecting dip for scrubbers, sponges, utensils 400 PPM

Degreaser/detergent brand:

Usage: Food contact surfaces, utensils 1 : 20 dilution

Smokehouse cleaner brand:

Usage: Smokehouse interior surfaces, racks, and screens 1 : 10 dilution

Hand cleaner brand:

Usage: Toilets and hand cleaning stations in all process areas

Lubricants brand:

Usage: Slicers, band saw, etc.

Appendix 3

An Illustrated Example of a HACCP Plan – Processing Cooked Shrimp* (See Chapter 3)

ASSEMBLING A HACCP TEAM AND ASSIGNING RESPONSIBILITIES (FORM #1)

Responsibility: Hazard identification

Name of the designee:

- 1.
 - 2.
 - 3.
-

Responsibility: CCPs determination

Name of the designee:

- 1.
 - 2.
 - 3.
-

Responsibility: Monitoring CCPs

Name of the designee:

- 1.
 - 2.
 - 3.
-

Responsibility: Verification of operations at CCPs

Name of the designee:

- 1.
 - 2.
 - 3.
-

Sample testing and verification:

Name of the designee:

- 1.
 - 2.
-

*Example taken from Canadian Food Inspection Agency QMP plan.

ORGANIZATION CHART AND NARRATIVE (FORM #2)

President/CEO	Overall responsibility in reviewing the HACCP plan with the Production, Quality Assurance and Sales Managers.
Prodn Manager	Responsible for everyday production and process operations of the facility. Reviews the HACCP plan with the President, Quality Assurance Manager and Sales Manager. Reports to the President.
Prodn Supervisor/s	Oversee the daily production and scheduling in the facility, reporting to the Production Manager. Responsible for overseeing all skilled and unskilled personnel in the production, storage, refrigeration and other areas involved in production.
QA Manager	Reports to the President of the company. Responsible for the HACCP plan and any changes related to the plan. Responsible for handling customer complaints. Oversees the Quality Assurance Technicians involved in sampling, testing and personnel assigned to specific duties in the HACCP plan. Reviews HACCP plan with the President, Production Manager and Sales Manager.
Purchase Manager	Reports to the President. Responsible for purchasing all the raw materials, packaging and labeling materials, etc. Develops product specifications in consultation with the Quality Assurance and Production Managers. Reports to the President.
Sales Manager	Reports to the President. Responsible for setting up and maintaining customer accounts, dealing with the bank, etc. Oversees all sales representatives and handling of customer complaints. Reviews HACCP plan with the President, Production Manager and Sales Manager.
Maintenance Manager	Reports to the Production Manager. Responsible for operational setup and maintenance of all the equipment in the facility.
Sanitation Manager	Reports to the Maintenance Manager. Responsible for developing the SSOPs in consultation with the Production and Quality Assurance Managers. Oversees the daily cleanup and sanitation of the facility following the SSOPs.
Personnel Manager	Reports to the President. Responsible for personnel matters including maintenance of employee health records.
Transport/Distribution	Reports to the President. Responsible for arranging transport, reefer trucks, ocean cargo, air cargo, etc.

This is only a guideline. Depending on the size of the company, one person may actually be handling more than one function.

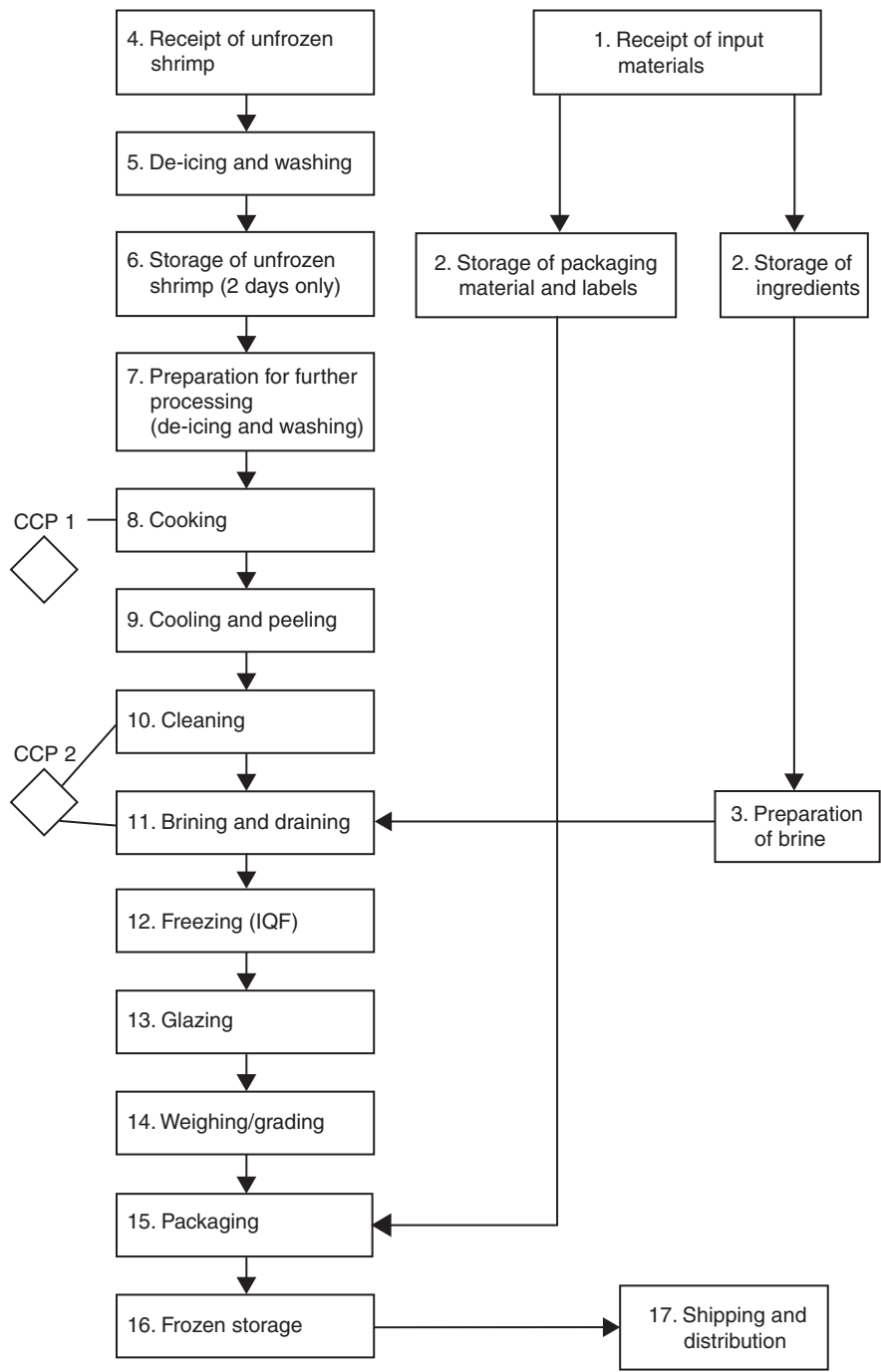
PRODUCT DESCRIPTION (FORM #3)

1. Product name(s)	Frozen cooked peeled shrimp
2. Source of raw material	Locally caught product
3. Important final product characteristics	Temperature < -18°C
4. Ingredients	Shrimp, glaze (salt + water)
5. Packaging	Polyethylene bags 300 g/800 g
6. How the end product is to be used	Product is thawed and normally consumed without further cooking
7. Shelf life	6 months after packaging
8. Where the product will be sold	Domestic retail International markets High-risk consumer group
9. Special labeling instructions	As per Fish Inspection Regulations, Food and Drug Regulations and international specifications
10. Special distribution control shelf life	Keep frozen Store at < -18°C

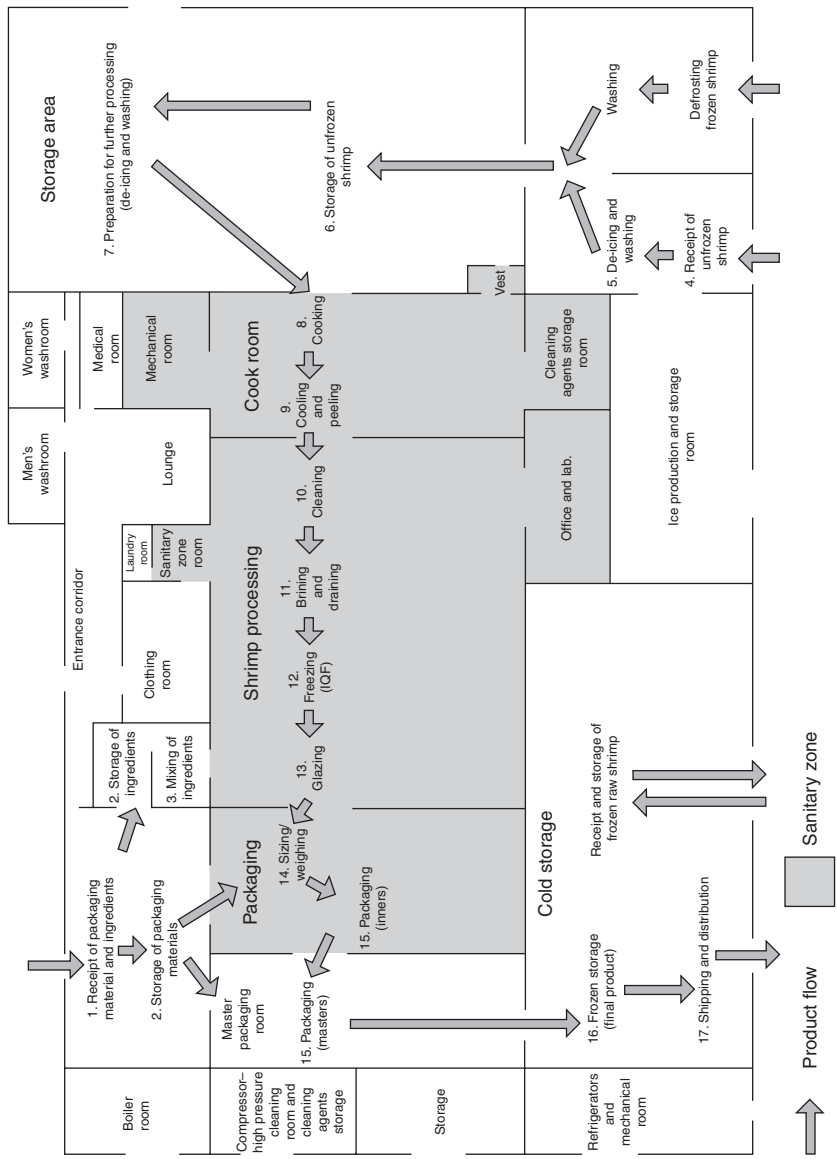
LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL (FORM #4)**Product name: Frozen cooked peeled shrimp**

Fresh headless shrimp		
Salt		
Polyethylene bags		
Potassium metabisulfite		
Waxed cardboard cartons		
Labels		

PROCESS FLOW DIAGRAM (FORM #5)



PLANT SCHEMATIC (FORM #6)



HAZARD ANALYSIS WORKSHEET (FORM #7)

Ingredient/processing step	Potential hazard introduced or controlled	Is the potential hazard significant?	Justification for inclusion or exclusion as a significant hazard	Preventive measures of the significant hazards
1. Receipt of input materials – packaging materials – salt	<i>Biological:</i> Potential for incoming materials to be contaminated during manufacture or transportation <i>Chemical:</i> Potential for incoming materials to be contaminated during manufacture or transportation <i>Physical:</i> Potential for incoming materials to be contaminated during manufacture or transportation	No No No	Not reasonably likely to occur; controlled by SOP – receipt and storage of packaging materials and ingredients Not reasonably likely to occur; controlled by SOP – receipt and storage of packaging materials and ingredients Not reasonably likely to occur; controlled by SOP – receipt and storage of packaging materials and ingredients	
2. Storage of input materials – packaging materials – salt	<i>Biological:</i> Potential for materials to become contaminated during storage <i>Chemical:</i> Potential for materials to become contaminated during storage <i>Physical:</i> Potential for materials to become contaminated during storage	No No No	Not reasonably likely to occur; controlled by SOP – receipt and storage of packaging materials and ingredients Not reasonably likely to occur; controlled by SOP – receipt and storage of packaging materials and ingredients Not reasonably likely to occur; controlled by SOP – receipt and storage of packaging materials and ingredients	

3. Preparation of brine	<i>Biological:</i> Water may be contaminated with pathogens	No	Not reasonably likely to occur. Controlled through prerequisite program
	<i>Chemical:</i> Industrial chemicals	No	Not reasonably likely to occur. Controlled by prerequisite program through SOP for receipt and storage of packaging material and ingredients
4. Receipt of unfrozen shrimp	<i>Physical:</i> None identified	n/a	
	<i>Biological:</i> Contamination with pathogens	No	The presence or growth of pathogens or parasites on the raw product is not considered significant for three reasons. The product will be cooked at a subsequent processing step, competition from dominant microflora, and the continuous nature of the process
	<i>Chemical:</i> Fuel oil	No	Not reasonably likely to occur. Controlled by SOPs
	<i>Physical:</i> Foreign matter	No	During harvesting and on-board handling, the raw material may become contaminated with pieces of plastic from nets or other materials from the vessel. However, the presence of this material is not considered significant as it will be removed through normal processing operations

continued

HAZARD ANALYSIS WORKSHEET (FORM #7) *continued*

Ingredient/processing step	Potential hazard introduced or controlled	Is the potential hazard significant?	Justification for inclusion or exclusion as a significant hazard	Preventive measures of the significant hazards
5. De-icing and washing	<i>Biological:</i> Contaminated wash water <i>Chemical:</i> Industrial chemicals <i>Physical:</i> None identified	No No n/a	Controlled by prerequisite programs Controlled by prerequisite program	
6. Storage of unfrozen shrimp on ice (up to 2 days)	<i>Biological:</i> Contaminated ice and water <i>Chemical:</i> Industrial chemicals <i>Physical:</i> Foreign material	No No No	Controlled by prerequisite program Controlled by prerequisite program Controlled by prerequisite program	
7. Preparation of shrimp for further processing (de-icing and washing)	<i>Biological:</i> Contaminated wash water <i>Chemical:</i> Industrial chemicals <i>Physical:</i> None identified	No No n/a	Controlled by prerequisite program Controlled by prerequisite program Controlled by prerequisite program	
8. Cooking (steam)	<i>Biological:</i> Pathogen survival (<i>Listeria</i>)	Yes	Pathogens that survive the cook will not be eliminated at subsequent processing steps. Processing time and temperature may not be sufficient to kill vegetative pathogens	1. Cooking 2. Employee training
9. Cooling and peeling (mechanical)	<i>Chemical:</i> Industrial chemicals <i>Physical:</i> None identified <i>Biological:</i> Post-process contamination with pathogens <i>Chemical:</i> Industrial chemicals <i>Physical:</i> None identified	No n/a No No n/a	Controlled by prerequisite program. SOP plant clean-up and sanitation Controlled by prerequisite program Controlled by prerequisite program	

10. Cleaning	<i>Biological:</i> Cross-contamination and recontamination with pathogens	No	Strict sanitation/hygiene controls for the sanitary zone in prerequisite programs will minimize contamination	Control process speed to ensure a rapid process (from cooking to freezing)
	Pathogen growth and toxin formation (<i>Staphylococcus</i>)	Yes	The growth of <i>Staphylococcus</i> must be controlled to prevent the formation of the <i>Staphylococcus</i> toxin	
11. Brining and draining	<i>Chemical:</i> Industrial chemicals	No	Controlled by prerequisite program	Control process speed and ensure no processing delays
	<i>Physical:</i> Shell	n/a	Trained personnel in place to remove undesirable pieces	
	<i>Biological:</i> Cross-contamination and recontamination with pathogens	No	Minimized by prerequisite program and SOP for preparation of brine	
	Pathogen growth (<i>Staphylococcus</i>)	Yes	Prerequisite program minimizes contamination with this pathogen but it will not prevent it entirely. The growth of <i>Staphylococcus</i> must be controlled to prevent the formation of the <i>Staphylococcus</i> toxin	
12. Freezing (IQF)	<i>Chemical:</i> Industrial chemicals	No	Controlled by prerequisite program	Not reasonably likely to occur due to the continuous nature of the process
	<i>Physical:</i> None identified	n/a		
	<i>Biological:</i> Pathogen growth	No	Controlled by prerequisite program	
13. Glazing	<i>Chemical:</i> Industrial chemicals	No		Controlled by prerequisite program
	<i>Physical:</i> None identified	n/a		
	<i>Biological:</i> Introduction of water-borne pathogens	No	Controlled by prerequisite program	
	<i>Chemical:</i> Industrial chemicals	No	Controlled by prerequisite program	
	<i>Physical:</i> None identified	n/a		

continued

HAZARD ANALYSIS WORKSHEET (FORM #7) continued

Ingredient/processing step	Potential hazard introduced or controlled	Is the potential hazard significant?	Justification for inclusion or exclusion as a significant hazard	Preventive measures of the significant hazards
14. Sizing	<i>Biological:</i> Cross-contamination and recontamination with pathogens <i>Chemical:</i> Industrial chemicals <i>Physical:</i> None identified	No No n/a	Controlled by prerequisite program	
15. Packaging	<i>Biological:</i> None identified <i>Chemical:</i> None identified <i>Physical:</i> None identified	n/a n/a n/a	Controlled by prerequisite program	
16. Frozen storage (final product)	<i>Biological:</i> None identified <i>Chemical:</i> None identified <i>Physical:</i> None identified	n/a n/a n/a		
17. Shipping and distribution	<i>Biological:</i> None identified <i>Chemical:</i> None identified <i>Physical:</i> None identified	n/a n/a n/a		

CCP DETERMINATION (FORM #8)

Process step	Hazard	Q. #1 Do control preventive measures exist? No – not a CCP – However, if control preventive measures are required to ensure safety then modify step, product or process.	Q. #2 Is the step specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level? No – to Q. #3 Yes – CCP	Q. #3 Could contamination with identified hazards occur in excess of acceptable levels or could these increase to unacceptable levels? No – not a CCP Yes – to Q. #4	Q. #4 Will a subsequent step eliminate identified hazards or reduce the likely occurrence to an acceptable level? No – CCP Yes – not a CCP	CCP Yes or No
8. Cooking	Pathogen survival (<i>Listeria</i>)	Yes	Yes			Yes
10. Cleaning	Pathogen growth and toxin formation (<i>Staphylococcus</i>)	Yes	No	Yes	No	Yes
11. Brining and draining	Pathogen growth and toxin formation (<i>Staphylococcus</i>)	Yes	No	Yes	No	Yes

HACCP PLAN (FORM #9)

Critical control point (CCP)	Significant hazard	Control/preventive measure	Critical limits	Monitoring	
				What?	How?
CCP 1 8. Cooking	Survival of <i>Listeria</i>	Heat process 5D <i>Listeria</i> reduction	2 min at 100°C will provide internal product temp. of 80°C for 1 s	Conveyor belt speed Temperature of cooker Recorder chart	Conveyor speed with stopwatch Recorder thermometer Visual check
CCP 2 10. Cleaning 11. Brining and draining	Growth of <i>Staphylococcus</i>	Rapid processing time	3 h maximum time between cooking and freezing	Product exposure to elevated temperature between cooking and freezing	Visual observation of index tag

Frequency	Who?	Records	Corrective action and records	Verification
After each break	QC staff	Conveyor belt monitoring record	1. Segregate affected product and evaluate for safety 2. Record nonconformity CA log book	1. Verify the CA by QC Manager daily 2. QC to review cook log 3. QC Manager to observe cooking process and compare data with those obtained by the cooker operator
Continuous	Automatic	Recorder chart	3. Sign and date the CA taken 4. Determine the source of the problem and take measures to prevent recurrence 5. Retrain employees if necessary	4. Verification of the heat process 5. Calibration of the temperature recorder
Hourly	QC staff	QC initial the recorder chart		
Hourly	QC staff	Process log	1. Segregate affected product and evaluate for safety 2. Record nonconformity CA log book 3. Sign and date the CA taken 4. Determine the source of the problem and take measures to prevent recurrence 5. Retrain employees if necessary	1. Verify the CA by QC Manager daily 2. QC to review cook log 3. QC Manager to observe cooking process and compare data with those obtained by the cooker operator

Appendix 4

Example of Detailed Product Specifications for Fresh and Frozen Green Headless and PUD Shrimp

Product specifications are one of the important requirements for every seafood importer when a product is received from those countries without an active Memorandum of Understanding.

PRODUCT SPECIFICATIONS FOR FRESH FROZEN GREEN HEADLESS AND PUD SHRIMP

1. Product identification

(A) Product definition:

Green headless is defined as the six tail segments of the shrimp, complete with shell, tail fin and vein. It is the shrimp in the shell without the head. The term 'green' refers to fresh or raw, and does not indicate the color of the shrimp.

High quality fresh, raw, headless, shell-on or peeled undeveined (PUD) tail-on or tail-off shrimp which shall be quick frozen only once. The flavor shall be that of a freshly caught shrimp of the desirable species specified in workmanship requirements. Shrimp shall not have any detectable, objectionable odor or discoloration.

(B) Product sizes:

Headless Size	lb net	Weight
U/15	5 lb	10/5 lb
16/20	5 lb	10/5 lb
21/25	5 lb	10/5 lb
26/30	5 lb	10/5 lb
31/35	5 lb	10/5 lb
36/40	5 lb	10/5 lb
41/50	5 lb	10/5 lb
51/60	5 lb	10/5 lb
61/70	5 lb	10/5 lb
71/90 PUD tail-on	5 lb	10/5 lb
91/110 PUD tail-on and tail-off	5 lb	10/5 lb
100/200 PUD tail-off	5 lb	10/5 lb
200/300 PUD tail-off	5 lb	10/5 lb

2. Packaging

- (A) Folding (inner) carton of appropriate size for packing 5 lb of shrimp.
- (B) Pack in clear durable polyethylene bag before packing the shrimp in carton.
- (C) Ten inner cartons shall be placed in one master carton. Inner cartons must be free of damage, sealed at all edges and free of all extraneous matter and odors. Master shall be durable in strength in order to withstand normal handling during shipment.
- (D) Each master carton must be plainly marked as to:
 Manufacturer's name:
 Species of shrimp:
 Weight (net):
 Production code: (should use the Julian Code Date System of XXXYY, where XXX is the day of the year and YY is the year)

3. Raw material source

Farm raised *Penaeus vannamei* and *Penaeus stylirostris*.

4. Net weight (net drained weight)

Should be 5 lb or more. (Does not include the empty container and glaze.)

5. Sensory quality

Flavor, odor and texture good to excellent after pouch cooking. Cooking is based on boiling unseasoned product in a boilable film type pouch immersed and cooked in boiling water to an internal temperature of 160°F (71°C).

6. Bacteriological standards

Sanitary procedures: Implement and follow at all times good manufacturing practices in order to assure the production of a good eating quality and wholesome product. This way you can be sure you can meet that microbiological requirements.

Microbiological requirements:

Test	n	c	m	M	Sample size
Standard plate count	5	2	<1 000 000/g	5 000 000/g	50
Coliforms	5	2	<1100/g	2400/g	50
<i>E. coli</i>	5	1	<3/g	10/g	50
Coagulase (+) Staph.	5	2	<200/g	1000/g	50
<i>Salmonella</i>	30	0	Negative	Negative	25

n = no. of samples of product per shipment or lot to be analyzed; c = maximum number of samples yielding counts above m, but lower than M; m = the microbiological count/gram which separates good quality from marginally acceptable quality. This figure shall not be exceeded for a particular lot for each test by the number of samples under the letter 'c'; M = the maximum microbiological count/gram which shall not be equal or exceeded by any sample, otherwise the lot shall be considered unacceptable.

7. Physical parameters

Count per pound: In the middle of the brackets. *Average count is calculated as follows:*

Total no. of whole shrimp/(net wt – wt of pieces, tailless and damaged).

Defects of pieces, tailless, broken/damaged should not exceed 5%.

Discolored shrimp, overall, percent by count should not exceed 10%.

Black spot on the shell: Excessive number of spots not to exceed 2%; moderate spots not to exceed 10%.

Cotton shrimp should not exceed 2%.

8. Workmanship requirements

Must meet US Grade Standards for Headless Shrimp. (See Chapter 6.)

9. Shipping and receiving

The product must be shipped and stored at -18°C (0°F) or below. Moisture loss from the surface during frozen storage may not exceed the moderate stage. Moderate dehydration can easily be scraped off with a fingernail. Shipments shall not consist of production codes exceeding 60 days. Day codes and quantity must be sent to the quality assurance ingredient lab prior to shipment.

10. Warranty

The seller warrants that all deliveries of material shall conform with the requirements of the US Food, Drug and Cosmetic Acts amended and applicable State Laws or Municipal Ordinances. The product shall have been manufactured, stored and shipped under good standards of sanitation in packaging free from dirt or contaminating substances and shall arrive at the buyer's plant in clean, undamaged condition.

Appendix 5

Raw Material Evaluation Worksheet

This step ensures compliance of imported products and provides the means for verification.

Product/supplier information:

Date _____	Lot No. _____	Inspected by _____
Brand _____	Country of origin _____	
Packer _____	Shrimp type _____	
Vendor _____	Process type _____	

Physical quality:

Sample No. _____	Declared net wt. _____	Actual net wt. _____
Declared size/count _____	Actual size/count _____	
% Peel _____	% Pieces _____	
Uniformity: % Large _____	% Normal _____	% Small _____
% Short weight _____	Beat up (Yes/No) _____	
% Spots on shell _____	Foreign matter (Yes/No) _____	
% Spots on meat _____	Dehydrated (Yes/No) _____	
% Swimmerets _____	Heated (Yes/No) _____	
% Missing tails _____	Bisulfite (Yes/No) _____	
Veins _____	Phosphate (Yes/No) _____	
% Spines _____	Bleaching (Yes/No) _____	
% Discolored _____	Salt (Yes/No) _____	
% Shell _____	Taste (OK/Off) _____	
Peelability (OK/Hard) _____	Bilge odor (Yes/No) _____	
Count range _____	Stale (Yes/No) _____	

Microbiological quality:

TPC _____; TC _____; FC _____; EC _____; CP *Staphylococcus*; *Salm* _____;
Sensory quality: _____

Accepted: (Quality Assurance); _____	(Purchasing) _____
Rejected: (Quality Assurance); _____	(Purchasing) _____

Any other remarks/recommendations: _____

TPC: Total plate counts; TC: Total coliforms; FC: Fecal coliforms; EC: *E. coli*; CP: Coagulase positive *Staphylococcus*; *Salm*: *Salmonella*.

Appendix 6

HACCP Regulations

Federal Register: 18 December 1995 (Volume 60: 242) pp 65095–65202

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule

21 CFR Part 123

Fish, Fishery products, Imports, Reporting and record keeping requirements, Seafood.

21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, title 21 CFR Chapter I is amended as follows:

1. New part 123 is added to read as follows:

PART 123 – FISH AND FISHERY PRODUCTS

Subpart A – General provisions

Sec.123.3	Definitions
123.5	Current good manufacturing practice
123.6	Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan
123.7	Corrective actions
123.8	Verification
123.9	Records
123.10	Training
123.11	Sanitation control procedures
123.12	Special requirements for imported products

Subpart B – Smoked and smoke-flavored fishery products

123.15	General
123.16	Process controls

Subpart C – Raw molluscan shellfish

123.20	General
123.28	Source controls

Authority: Secs. 201, 402, 403, 406, 409, 701, 704, 721, 801, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393); Secs. 301, 307, 361 of the Public Health Service Act (42 U.S.C. 241, 242i, 264).

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 molluscs, 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 US owner or consignee at the time of entry into the United States, or the US 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) (1) Processing means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, 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 Page 65198 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 together, 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 thus that 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 a food 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 introduced 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 accordance with Sec. 123.8(a);
 - (7) Provide for a record keeping 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 processor's 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 either 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 record keeping 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 immediately 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 view 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 minimum, 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) Record keeping. 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 record keeping 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 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 US 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 material, 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 contamination 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.
- (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 understanding (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 US 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 imported fish or fishery product is or was processed in accordance with the requirements 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 US 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 7

Abbreviations Used in This Book

AOAC	Association of Official Analytical Chemists
APC	Aerobic Plate Count
AQL	Acceptable Quality Level
ASEAN	Association of South East Asian Nations
ATP	Adenosine Triphosphate
BOD	Biological Oxygen Demand
BT	Black Tiger
CA	Corrective Action
CAC	Codex Alimentarius Commission
CCP	Critical Control Point
CFN	Central File Number
CGMP	Current Good Manufacturing Practices
CL	Critical Limit
CMC	Carboxymethylcellulose
CP	Control Point
CVM	Center for Veterinary Medicine
DDE	Dichlorodiphenylethane
DDT	Dichlorodiphenyltrichloroethane
DHHS	Department of Health and Human Services
DIS	Draft International Standards
DLP	Direct Labeled Probe
DO	Dissolved Oxygen
EDTA	Ethylenediaminetetraacetic acid
EEZ	Exclusive Economic Zone
ELISA	Enzyme Linked Immunosorbent Assay
EMS	Environmental Management System
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FD&C	Food, Drug and Cosmetics Act
FTC	Federal Trade Commission
GATT	General Agreement on Tariffs and Trade
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
HA	Hazard Analysis
HACCP	Hazard Analysis Critical Control Point
HAV	Hepatitis A Virus
HL	Headless
HO	Head-on
HTST	High Temperature Short Time
IQF	Individually Quick Frozen

IQL	Indifference Quality Level
ISO	International Organization of Standards
LACF	Low Acid Canned Foods
MBPW	Modified Buffered Peptone Water
MO	Microorganisms
MOU	Memorandum of Understanding
MP	Monitoring Procedure
NAFIQACEN	National Fisheries Inspection and Quality Assurance Center
NAS	National Academy of Sciences
NCQSTAP	National Center for Quality Standards and Testing of Aquatic Products
NOAA	National Oceanic and Atmospheric Administration
NSSP	National Shellfish Sanitation Program
OC	Operating Characteristic
OECD	Organization for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PABA	Para-aminobenzoic Acid
PCB	Polychlorinated biphenyls
PCR	Polymerase Chain Reaction
PD	Peeled Deveined
PPM	Parts Per Million
PPO	Polyphenol Oxidase
PPT	Parts Per Thousand
PSI	Pounds per Square Inch
PUD	Peeled Undeveined
PUDT/PTO	Peeled Undeveined Tail-on/Peeled Deveined Tail-on
PUFI	Processed Under Federal Inspection
QA	Quality Assurance
QMP	Quality Management Program
RMD	Rapid Microbial Detection
RQL	Rejectable Quality Level
RSW/CSW	Refrigerated Seawater/Chilled Seawater
SEAQIP	Seafood Export and Quality Improvement Project
SIFE	Sanitarily Inspected Federal Establishment
SOP	Standard Operating Procedure
SPC/SQC	Statistical Process Control/ Statistical Quality Control
SPF	Specific Pathogen Free
SSOP	Standard Sanitation Operating Procedure
STPP	Sodium Tripolyphosphate
TCA	Trichloroacetate
TDE	Trichlorodiphenylethane
TED	Turtle Exclusion Device
TPC	Total Plate Count
TVC	Total Viable Count
USDA	United States Department of Agriculture
USDC	United States Department of Commerce
USFDA	United States Food and Drug Administration
VIA	Visual Immunoassay
WHO	World Health Organization

Appendix 8

Recommendations for Factory Vessels

Fishing vessels that do not process at sea are exempted from mandatory HACCP regulations. Beheading of shrimp solely for holding on board a harvest vessel and on-board freezing are exempted. However, factory vessels are not exempt. The following recommendations are provided as general guidelines for ocean harvested shrimp.

Sanitation

All fish receiving areas, equipment, containers and utensils must be cleaned and disinfected at least once a day while the vessel is operating and immediately following discharge of the product from a vessel. Cleaning must be performed with potable water or clean seawater. Following cleaning operations, all equipment and surfaces must be disinfected then rinsed to remove the disinfectant. Harbor water, or water from alongside the dock where the vessel is tied up, must never be used for cleaning purposes as it is usually polluted. This is also usually true for water in close vicinity to towns, villages, industrial plants, fish plants and freezer/factory ships.

A permanent cleaning and disinfecting schedule should be drawn up to ensure that all parts of the boat and equipment are cleaned appropriately and regularly. The most effective method of cleaning is to rinse with a high pressure jet of cold water followed by a scrub with a stiff brush using an acceptable detergent; rinse with cold water; sanitize with cold water containing hypochlorite solution or another acceptable disinfectant; rinse again to remove the disinfectant.

Hand washing facilities shall be equipped with running water, liquid or powdered soap, and single service towels. As a general guide, one marine type flush toilet and one washbasin should be provided for every ten crew members. The hand washing facilities should be located close to the product handling area to encourage frequent hand washing. The use of the galley sink for hand washing is acceptable.

The waste discharge must drain overboard, be equipped with a check valve if necessary, be situated on the opposite side from water intakes, and further towards the stern in order to minimize the possibility of contamination when the vessel is in forward motion. A washbasin draining into a pail is not recommended.

Factory vessels should employ sanitation and handling practices equivalent to similar shore based facilities.

Fisherman should be well trained in the use of disinfectants and equipment for cleaning and should be knowledgeable in the significance of contamination and the hazards involved.

Protection of the catch

- (a) Sun and weather: Vessels with holds will be required to have close fittings, preferably insulated covers constructed of approved material. These will reduce air circulation and deter the melting of the ice. Approved materials are stainless steel, corrosion resistant aluminum, high-density plastic, fiberglass reinforced plastic and smooth coated wood.

Smaller vessels with open holds will be required to have some form of approved cover, or approved covered boxes. Nonabsorbent plastic or rubberized covers, if adequately secured, may be used for short trips. Canvas tarpaulins must be avoided.

- (b) Bilge water and other contamination: Fish storage areas shall be constructed to provide drainage and to ensure that bilge water and other contaminants do not come in contact with fish and ice. False bottoms or shelving are therefore required. Contamination from other sources such as grease and oil, etc., in the ice and fish storage areas could result in the loss of the catch. Therefore equipment such as chain drives, drive shafts and bearings in fish storage areas shall be relocated or enclosed to protect fish and ice from contamination and to minimize this risk.

It will not be necessary to enclose below deck bilge pumps, hydraulic lines and hydraulically operated fish pumps provided that they are adequately maintained and coated with approved epoxy paint. Rubber hoses must not be painted as the flexing causes the paint to flake off.

- (c) Physical damage: Shelving must be provided for vessels in which the catch is iced in holds to a depth greater than 60 cm. However, crustaceans such as shrimp should be stored at depths not more than 60 cm. Separate storage facilities must be provided for by-products.

Service facilities such as fuel lines, fueling ports, waste disposal lines and fuel storage tanks shall not be located in a fish storage area. If these cannot be relocated, they shall be totally enclosed or watertight. Storage facilities will allow the drainage of melt water.

- (d) New vessels: Fish contact surfaces of holds, shelving land dividers, boxes and chilled water tanks shall be constructed of noncorrodible, smooth surfaced, approved material impervious to water. Examples are stainless steel, seawater resistant aluminum alloys, high-density plastic, polyurethane coated cement or fiberglass reinforced plastic.

Note: Holds, pens, boxes and chilled water tanks coated with just epoxy are not adequate.

- (e) Existing vessels: Special purpose, light colored, acceptable coating may be applied to the surfaces of existing wooden or steel holds, checkers, and large holding containers or pens not regularly removed from the vessels. If there are severe cracks, crevices or gouges, the hold must be relined prior to applying the coating. Such coatings must be kept in good condition during the fishing season.
- (f) Boxing at sea: If boxes are used at sea, they should be of plastic material and constructed in such a way as to provide drainage and protection of the product from damage when stacked.

Construction of bulkheads

The insulating material in use must minimize heat transfer into the storage areas. A minimum 'R' factor of 10 will be considered acceptable for bulkheads of fresh fish storage areas. Frozen storage areas of vessels must be insulated to a minimum 'R' factor of 20.

All insulating material must be properly installed. Any ice melt water, blood or slime seeping through the fish hold lining will reduce the efficiency of the insulation and this will, in turn, lead to an increase in the temperature of the product. All insulation must be properly covered with approved impervious hold lining material. All joints must be watertight.

Table 1. R-values for various types of insulating material (per inch thickness) commonly used on vessels

Type of insulation	R-value average
Ordinary wood	1.00
Urethane foam	6.25
Glass fiber	4.00
Expanded polystyrene depending on density	4.00–5.00
Foam glass	2.60
Expanded perlite	2.70
Wood fiberboard	1.67
Styrofoam depending on density	4.00–5.00

Note: R-values can be calculated by multiplying the above figures by the thickness (in inches) of the insulating material to be applied.

For example: Calculated R-value for urethane foam (3 inches thickness) will be $6.25 \times 3 = 18.75$.

The above table is intended to serve as a guideline. Vessel owners should obtain specific R-values of the insulating material intended to be used, from their contractors or suppliers.

Fish handling equipment and practices

All processing equipment such as chutes, conveyors, washers, tables and utensils shall be constructed of approved material, examples being stainless steel, salt water resistant aluminium alloys, high-density plastic and fiberglass reinforced plastic. Galvanized metal and epoxy-coated wood will not be adequate for the construction of such equipment. The equipment shall be accessible, or easy to dismantle for cleaning of all parts.

For vessels with below deck storage, rather than throwing or dropping the product into the hold, chutes or other devices shall be provided to minimize physical damage.

The ice requirement ranges from 50% to 100% of the catch weight depending upon the vessel construction, weather conditions, water temperatures and trip length. Product held in pens or boxes shall be iced at a recommended ratio of at least one part flaked or finely divided ice to three parts of the product. The ice shall be made of water from an approved source to prevent contamination of the vessel hold and the catch and shall be evenly distributed. A sufficient layer of ice is

required between the product and the vessel sides. Used or otherwise contaminated ice left over from a fishing trip must be removed from the vessel as soon as the catch is unloaded. It must not be used on future trips as it is contaminated with ice melt water, blood and slime, all of which contain large numbers of spoilage bacteria.

Refrigerated or chilled seawater systems (RSW/CSW) or other approved methods for rapidly cooling and holding fish at 38°F or lower may be used. Cool ambient temperatures or refrigeration systems producing cool air, however, are not suitable replacements for ice in cooling a product in bulk. Where RSW/CSW systems are installed on a vessel, such systems shall be made of approved materials such as stainless steel, high-density plastics, seawater resistant aluminum and copper based alloys. The design must allow an easy introduction and effective circulation of the cleaning and disinfecting solutions. All areas must be amenable to proper cleaning procedures. RSW systems must have sufficient compressor capacity to prevent significant rise in temperature of the pre-chilled seawater or brine solution when the holding tanks are being loaded with freshly caught product. Due to the difficulty in controlling the temperature precisely, the system must continually operate in a manner that would reduce the product temperature to between 30°F and 36°F and maintain it.

Freezing facilities on a vessel shall be of such a capacity to adequately freeze the catch. An air-blast freezer should be capable of freezing by means of air current at a temperature of -30°C or colder, moving at a velocity of not less than 125 m/min over the product surface. A brine freezer should be capable of freezing the product in a well-agitated solution at a temperature of -15°C or colder. A suggested freezing rate of penetration is 0.25 inch/h. The type of packaging, thickness of the product and procedures for loading of product into the freezer must be such that the freezing rate and the time limit specified can be adhered to. The product must at all times be coated with a good quality glaze made from an approved water source, or tightly wrapped in approved impervious packaging material to protect against dehydration and oxidation.

Appendix 9

Celsius–Fahrenheit Temperature Conversions

C		F	C		F	C		F
–17.8	0	32.0	1.67	35	95.0	20.6	69	156.2
–17.2	1	33.8	2.22	36	96.8	21.1	70	158.0
–16.7	2	35.6	2.78	37	98.6	21.7	71	159.8
–16.1	3	37.4	3.33	38	100.4	22.2	72	161.6
–15.6	4	39.2	3.89	39	102.2	22.8	73	163.4
–15.0	5	41.0	4.44	40	104.0	23.3	74	165.2
–14.4	6	42.8	5.00	41	105.8	23.0	75	167.0
–13.9	7	44.6	5.56	42	107.6	24.4	76	168.8
–13.3	8	46.4	6.11	43	109.4	25.0	77	170.6
–12.8	9	48.2	6.67	44	111.2	25.6	78	172.4
–12.2	10	50.0	7.22	45	113.0	26.1	79	174.2
–11.7	11	51.8	7.78	46	114.8	26.7	80	176.0
–11.1	12	53.6	8.33	47	116.6	27.2	81	177.8
–10.6	13	55.4	8.89	48	118.4	27.8	82	179.6
–10.0	14	57.2	9.44	49	120.2	28.3	83	181.4
–9.44	15	59.0	10.0	50	122.0	28.9	84	183.2
–8.89	16	60.8	10.6	51	123.8	29.4	85	185.0
–8.33	17	62.6	11.1	52	125.6	30.0	86	186.8
–7.78	18	64.4	11.7	53	127.4	30.6	87	188.6
–7.22	19	66.2	12.2	54	129.2	31.1	88	190.4
–6.67	20	68.0	12.8	55	131.0	31.7	89	192.2
–6.11	21	69.8	13.3	56	132.8	32.2	90	194.0
–5.56	22	71.6	13.9	57	134.6	32.8	91	195.8
–5.00	23	73.4	14.4	58	136.4	33.3	92	197.6
–4.44	24	75.2	15.0	59	138.2	33.9	93	199.4
–3.89	25	77.0	15.6	60	140.0	34.4	94	201.2
–3.33	26	78.8	16.1	61	141.8	35.0	95	203.0
–2.78	27	80.6	16.7	62	143.6	35.6	96	204.8
–2.22	28	82.4	17.2	63	145.4	36.1	97	206.6
–1.67	29	84.2	17.8	64	147.2	36.7	98	208.4
–1.11	30	86.0	18.3	65	149.0	37.2	99	210.2
–0.56	31	87.8	18.9	66	150.8	37.8	100	212.0
0	32	89.6	19.4	67	152.6	38.3	101	213.8
0.56	33	91.4	20.0	68	154.4	38.9	102	215.6
1.11	34	93.2	20.6	69	156.2	39.4	103	217.4

Note: The whole numbers refer to the temperature in either degrees Celsius or Fahrenheit, which is to be converted to the other scale. If converting from degrees Celsius, the center column is the temperature converting from, and the right column is its equivalent in degrees Fahrenheit. When converting from degrees Fahrenheit, the center column is the temperature converting from, and the left column is its equivalent in degrees Celsius.

Appendix 10

Conversion Factors

Multiply	By	To obtain
in	25.4	mm
in	2.54	cm
in	0.0254	m
ft	0.3048	m
ft	304.8	mm
ft	30.48	cm
ft ²	0.0929	m ²
in ²	0.0006452	m ²
acre	4047.0	m ²
acre	0.4047	ha
ft ³	0.0283	m ³
yd ³	0.7646	m ³
gal	3.785	l
gal	0.003785	m ³
ft/s	0.3048	m/s
ft ³ /s	0.0283	m ³ /s
ft ³ /s	28.3	l/s
gpm	0.00006308	m ³ /s
gpm	0.06308	l/s
lbf	4.448	N
ton (2000 lbf)	8896.0	N
ft-lbf	1.356	N-m
slug	14.49	kg
lbm	0.4536	kg
lbm/ft ³	16.02	kg/m ³
lbf/ft ²	47.88	N/m ²
lbf/in ²	6895.0	N/m ²
lbf/ft ³	157.1	N/m ³
ft-lbf	1.356	J
ft ² /s	0.0929	m ² /s
lbf-s/ft ²	47.88	N-s/m ²
hp	0.747	kW
BTU	1055.0	J

Index

- Academy of Health Sciences 110
acriflavin hydrochloride 100–101
active memorandum of understanding
 17, 155
actual hazards 53
additive formulation 59–60
adenosine triphosphate 91, 159
adequacy of the microbiological and/or
 chemical safety 117
advanced decomposition 75
advisory procedures 148
aerobic plate count (APC) 90, 159
aerosols 123
affirmative action 17
agricultural pollution 32–33
air conditioning unit 98, 102
air curtain 18, 107
airborne contamination 19
air-exchange 19
American Soybean Association 108
amnesic shellfish toxin 31
animal feces 93
animal food labeling 110
ANSI/NSF 18, 107
Anthoymidae 80
antibiotics 12, 31, 88
APC *see* aerobic plate count

aquaculture 3–5, 9, 11–13, 31, 40, 72,
 84, 105, 107–108, 110, 128
aquatic turtle 147
arrival of the raw material 114
ascorbates 30–31
assay time 94
Association of Official Analytical
 Chemists 36, 107, 159
Australian Quarantine Inspection
 Service 105

Bacillus cereus 30, 89
bacteria 15, 22, 24–25, 29–30, 87–91, 94,
 97, 148, 164
bacterial
 contamination 91
 growth 30, 88
 ice nucleation detection 94
 odors 74
bacteriological tests 91
banana prawns 41
Band-aids 31
BAX 94
best possible safety 12
better production methods 105
biological
 contaminants 154
 hazards 13, 29, 34
Biotrace/Ecolab 91
bisulfite 43–44, 54–55, 74, 78, 145
bivalve shellfish 13
black scavenger 80
black spot 77–78, 83–84, 144
black tiger 41–42, 159
blast freezing 31, 52
brackish rivers 42
Brazil pinks 41
breeding 20, 28, 48–50, 63, 78, 80
brining 128, 132, 137, 139–140
 time 140
butterfly 42, 50, 78
butterfly tail-on 78
byproduct plant 21

Calliphoridae 80
Campeche banks 41
Campylobacter 30, 89
Canaccidae 80
catarrhal jaundice 30

- Central File Number (CFN) 8, 159
- Certification
- bodies 9
 - molluscan shellfish processors 148
 - number 147, 157–158
 - number of the packer 157–158
- chemical
- contamination 32, 78, 149, 156
- chlordane 31
- chlordecone 31
- chlorine 20, 22–24, 30–31, 74, 78
- chlorine dioxide 20
- chloropid 80
- Chloropidae 80
- ciguatoxin 31
- Clostridium botulinum* 30, 38, 89, 150, 156
- Clostridium perfringens* 30, 89
- Codex Alimentarius 8, 13, 17, 29, 107, 110, 159
- Codex Committee, recommendations 12, 106
- color
- additives 110, 149
 - card 96, 98, 100, 102–103
 - development 98, 102
- consumer 151–152
- complaints 7, 37, 151
 - packs 28
 - risk 67
 - sensitivity 12
 - tests 148
- conformance quality 66
- contaminants 3, 5, 13, 29, 32, 34–35, 113, 154, 162
- contamination 11, 13, 15–17, 19–21, 24–25, 31–35, 54–55, 57, 59, 61, 63, 78, 91–92, 114–119, 122, 135–137, 139, 149, 154, 156, 161–163
- detectable levels of 54, 59
 - sources 25, 34
- control antigens 95–96, 100–101
- conventional methods of analysis 99
- cooking time 39, 47, 51.
- Cosmetics Safety Act 3
- Council of the European Communities 110
- cross-contamination 17, 32, 61, 96, 101, 114, 119, 122, 138, 154
- crystal violet 89–90
- customer
- complaint system 10
 - inspection 11
- daily sanitation report 25, 111, 127
- dairy 72, 105
- dairy industries 105
- day codes 144
- de-icing 132–133, 136
- deveined 42, 45, 47, 52, 77, 79, 81, 160
- deveining machine 46–47
- dieldrin 31
- Drugs Act 124
- E. coli* see *Escherichia coli*
- EDTA 104, 159
- employee health 17, 130, 154
- control of 154
 - training 57, 59
- employees 14, 19, 24, 28, 61–62, 64, 121–122, 141
- appropriate training 121
 - handling raw product 62
- Enterobacter* 92
- environmental management system 11, 159
- Environmental Protection Agency 5, 23, 36, 159
- requirements 23
- EPA see Environmental Protection Agency
- Ephydridae 80
- epidemic jaundice 30
- equipment
- calibration 57, 60
 - inspection 120
 - maintenance log 58
 - sterile 91–92
- Escherichia coli* 22, 30, 87, 89, 92–93, 143, 145
- EU Export Health Certificate 8
- EU Health Certificate 8

- FAO *see* Food and Agriculture Organization
- FDA *see* Food and Drug Administration
- Federal
 - Register 1, 5, 107, 146
 - Regulations 7, 16, 107
 - Trade Commission 5, 159
- Federal Clean Water Act 5
- ferric ammonium citrate 101
- fiberglass 18, 162–163
- finished product distribution systems 151–152
- fish
 - inspection regulations 131
 - plants 110, 161
 - pumps 162
 - storage areas 162–163
 - tissue 90
- fish handling
 - equipment 163
 - procedures 3
- fisheries management policies 4
- fishery
 - product processing methods 29, 108
 - products 5, 7–8, 13, 26, 29, 75, 107–108, 110, 146–150, 154–156
 - vessels 9, 105, 161
- floor coating systems 18
- floor drainage 115
- food
 - contamination 19
 - handlers 30, 121
 - handling 114, 119, 122
 - handling areas 119, 122
 - hygiene 12–13, 17, 29, 106–107, 121
 - encouraging food hygiene 12
 - infection 31
 - ingredients 84, 109
 - labeling 3, 110
 - plant 25, 154
 - poisoning 15, 31, 103
 - processing 1–2, 30–31, 107, 116
 - producers 1, 105
 - production accreditation 105
 - safety enhancement program 107, 113
- food additives 3, 13, 59, 110
- Food and Agriculture Organization 11–13, 40, 106–107, 109–110, 159
- Food and Drug Administration 1–3, 5–8, 12, 16, 29, 32, 35–36, 55–56, 75, 79–80, 84, 99, 105, 107, 109–110, 159
 - compliance guidelines 56
 - compliance policy 75
 - inspection 5, 110
 - inspection operations manual 110
 - inspectors 7
 - investigator 8
 - literature 32
 - method 99
- good manufacturing practices 3, 7, 16, 69, 110, 143, 159
- grower's certification 31
- HACCP
 - activities 13
 - application 12–13
 - certification of aquaculture enterprises 13
 - concept 9, 13
 - decision tree 32
 - documentation 6
 - implementation 8, 109
 - inspection system 1–2
 - legislation, partial 105
 - plan 4, 7, 15–17, 22, 26–27, 29, 31, 33, 35–39, 53, 111, 129–130, 140, 146, 148–152, 154–155
 - agreed upon 39
 - development 26, 35, 53
 - generic type 153, 154
 - reassessment 151
 - verification 36
 - principles 2, 8, 17, 27, 29, 35, 53, 105, 108–110, 153
 - process 37
 - program 7, 72
 - quality assurance systems 106

- HACCP (*Cont'd*)
 - records 17, 39
 - regulations 6–8, 16–17, 25, 111, 146, 161
 - regulatory model 109–110
 - rules 16, 49
 - seven principles of 26, 29
 - system 11, 108
 - implementation 5, 14, 85, 90
 - international use 12, 106
 - training manual 29
 - user's manual 109
 - worldwide acceptance 105
- hair covering 122
- handling raw product 61–62
- handwashing stations 115
- harvesting information 148, 158
 - hazard 31, 34, 120
- Hazard Analysis Critical Control Points *see* HACCP
- hygiene
 - of foodstuffs 29, 110
 - testing 90
- hygienic
 - condition 19
 - handling of food 21, 121
 - operations 114
 - practices 21
- immunoassay 94, 99, 102–103, 160
- immunological tests 90
- immunosorbent assay 94, 159
- impact resistance 18
- importer 3, 5–8, 17, 28, 38–39, 75, 105, 142, 147, 152–153, 155–156
 - improvement project 14, 160
 - manager 130
 - reports 130
 - of seafood 109
 - purposes 72
 - technicians 130
- independent
 - audits 9
 - panel of food safety 29
- industrial pollutants 34
- inorganic contamination 11
- insanitary
 - conditions 155
 - objects 154
- insect fragments 31
- inspection
 - activity 114
 - cost 66
 - errors 66
 - methods 110
 - programs 2–3, 124
 - service 5, 105, 108
- International Code of Practice 13, 17, 110
- International Standards Organization (ISO) 1, 9–11, 108–109, 160
- ISO *see* International Standards Organization
- Klebsiella* 92
- label of origin 5
- labeling 17, 154
 - nutritional 3
 - packaging 5
- Labeling Act 3, 107
- labeling instructions, special 131
- labels 5, 131–132, 149
- Listeria* 22, 30, 87–90, 98–100, 103, 136, 139–140
 - antibodies 100
 - antigens 99–100
 - infection 98
 - visual immunoassays 103
- Listeria grayi* 99
- Listeria innocua* 99
- Listeria ivanovii* 99
- Listeria monocytogenes* 22, 30, 89, 98, 99
- Listeria murrayi* 99
- Listeria seeligeri* 99
- Listeria welshimeri* 99
- Macrobrachium rosenbergii* 41
- manufacturing costs 2
- marine
 - environmental monitoring 4
 - environments 40
 - resources 11

- marketing 4–5, 12, 110
 - material 18–19
- maximum residue limit 124
- maximum shelf life 16
- mechanical
 - freezing 52
 - grading 44
- Metapenaeus affinis* 41
- microbial
 - contamination 13, 16, 54, 57, 59, 61, 63, 91
 - growth 64, 88–89
- microbiological
 - analysis 109
 - cleanliness of the area 38
 - contamination 122, 149, 156
 - criteria 29, 33, 108–109
 - indices 36
 - methods 87
 - quality 87, 89, 91, 93, 95, 97, 99, 101, 103, 145
 - requirements 143
 - specifications 109
 - standard 69
 - test 91, 124
 - testing 38, 87, 90, 124
- mushy texture 78–79, 81
- National Marine Fisheries Service 2, 4, 109–110
- National Quality Management 13
- National Research Council 109
- National Sea Grant College Program 127
- National Seafood HACCP Alliance 108
- National Seafood Inspection Laboratory 109–110
- National Shellfish Sanitation Program 3, 160
- natural
 - color 40
 - flavors 47
 - toxins 31, 149, 156
- net weight 52, 59, 65, 76–77, 143
- nonfood compounds 23, 108
- odor
 - ammonia 74
 - bacterial 74
 - cosmetic 73
 - decomposition 74, 75
 - ‘earthy-like’ 74
 - fishy 75
 - foreign 73
 - musty 74
 - objectionable 17
 - obnoxious 19
 - strong putrid 74
- off-flavor 81
- off-odor 73–74, 81
- on-board
 - freezing 161
 - handling 135
- organoleptic examination 73, 75
- oxygen, absence of 90
- packaging 3–5, 15, 19–21, 26–28, 52, 59, 107, 114, 116–120, 123–124, 130–135, 143–144, 154, 164
 - areas 19, 114, 116
 - material rotation 118
 - materials 15, 20–21, 27–28, 59, 114, 116–120, 123–124, 134, 135, 154.
- Pandalus borealis* 40
- Pandalus dispar* 40
- Pandalus platyceros* 40
- Pandulus jordani* 40
- Pandulus orientalis* 41
- pathogen
 - growth 54, 61, 137
 - reduction 108
- pathogenic
 - bacteria 30, 91
 - contamination 19
 - microorganisms 2, 54, 88–89
- pathogens 29–30, 87–90, 94, 135–138
- peeling defects 78
- peeling/deveining 57–58
- Penaeus aztecus* 41
- Penaeus brasiliensis* 41
- Penaeus californiensis* 41
- Penaeus chinensis* 41
- Penaeus duorarum* 41

- Penaeus indicus* 41
- Penaeus merguensis* 41
- Penaeus monodon* 41
- Penaeus notalis* 41
- Penaeus occidentalis* 41
- Penaeus schmitti* 41
- Penaeus setiferus* 41
- Penaeus* spp 49
- Penaeus stylirostris* 41, 143
- Penaeus vannamei* 41, 143
- pesticides 5, 12, 17, 21, 31–33, 35, 124, 149, 154
- plant
 - cleanliness 98
 - plant environment 15, 26, 149–150
 - plant expansion 22
- product
 - cost 65
 - ingredient list 82
 - odors 73
 - properties 27
 - quality 4, 47
 - safety 21, 37, 121
 - sizes 142
 - specifications 38, 75, 111, 130, 142, 155
 - temperature 54–55, 164
 - unsafe 59
- production
 - areas 24, 115, 122
 - better methods 105
 - code 143, 144, 153
 - staff 21
- public health 6, 15, 109, 146–147, 156–157
- QA *see* quality assurance
- quality 67–68, 143, 159
 - level 67–68, 159–160
 - management 9–10, 12–13, 108, 160
- quality assurance 9, 14, 16, 21, 72, 106, 108–109, 130, 144–145, 160
 - center 14, 160
- random sample 66–67
- range of effects 30
- raw material 13, 15, 26, 38, 49, 53, 65, 78, 111, 114, 131, 135, 143, 145
- ready-to-use form 91–92
- recall procedure 125–126
- receiving
 - area 54
 - records 56
 - records, disclosure 110
- refrigeration systems 164
- regulatory authorities 60, 62, 64
- regulatory standards 5
- rejectable quality level 67–68, 160
- rejection
 - of a conforming lot 67
 - of the entire lot 66
- resealable pouch 95, 100
- resealing 96–97, 100
- risk of recurrence 37, 151
- risk-assessment techniques 1
- risks of passing defective lots 66
- rodent filth 31
- rodenticides 31
- Salmonella* 30, 38, 65, 87–90, 93–95, 97, 103, 143, 145
 - antibodies 95
 - antigen 94–95
 - detection 94
- sample
 - size 66, 68–70, 143
 - testing 129
 - unit 68–69
- sampling plans 65, 67, 69–71
- sand veins 78
 - removal 42
- sanitary
 - conditions 6, 65, 90, 92, 148
 - facilities 17, 19, 115
 - hand drying equipment 115
 - inspections 3
 - regulations of the EU 13
 - zone 137
- sanitation
 - log 55, 58, 61, 62, 64
 - manager reports 130
 - measures 16
 - monitoring 55, 154
 - records 155

- practices 16, 30–31
- procedures 7, 15, 21–22, 25
- program 2–3, 17, 121, 123, 160
- standards 110
- system 22, 108
- sanitizing
 - equipment 123
 - facilities 17, 116
 - maintenance 57, 119
 - procedure 117
 - solution 24
- seafood hazards 29
- seafood inspection program 4, 110
- sealable plastic container 96, 101
- shelf life 16, 28, 52, 89, 101, 131, 156
- shrimp
 - culture 11–12, 16, 31, 33, 53
 - flesh 74, 78–79
 - head 45, 74, 78
 - meat 84
 - piece 77
 - processor 65, 87
 - tail 47
 - weight 76, 143
- sodium alginate 52
- sodium bisulfite 43–44, 74, 78
- sodium chloride 148
- sodium metabisulfite 84
- sodium phosphate 96
- sodium tripolyphosphate 47, 82–83, 160
- special dietary foods 110
- spoilage 16, 30, 54, 89, 118, 164
- Staphylococcus aureus* 30, 63, 69, 89, 103–104
 - growth 63
 - populations 103
- Staphylococcus gallinarum* 94
- statistical procedures 36
- statistical process/quality control 71
- storage
 - areas 23–24, 123, 162–163
 - capacity 153
 - facilities 21, 162
 - packaging 132, 134–135
 - raw materials 20
 - temperature 28, 39
 - temperature/humidity 28
- sulfite
 - sensitive 84
 - test 84
- sulfites 30–31, 83–84
- supervisory checks 60–61
- supplier's
 - certificate 13
 - certification 35
- temperature
 - logs 55–56, 58
 - requirements 123
- test protocols 36
- test sample 96, 101
- texture terms 40
- texture, soft/mushy 78
- thermal
 - processing 30–31
 - treatment 126
- thermometer check/calibration 38
- toilets 19, 116, 122, 127–128, 154
- toxin formation 38, 63, 139
- training 7, 15, 151
- typhoid fever 94
- ultraviolet radiation 30–31
- unacceptable
 - consumer risk 29, 32
 - product 3
- unapproved use 149
- undercooked food 31
- undeveined 42, 76, 79, 142, 160
- verification
 - accuracy
 - activities 37–39, 151–152, 154, 156
 - compliance 6
 - operations 129
 - procedures 27, 35, 37–38, 150, 152, 155–156
- veterinary medicine 3, 107, 159
- Vibrio cholera* 30, 89
- Vibrio parahaemolyticus* 89
- visual checks 65
- wash solution 95–96, 98–99, 101–102

- waste
 - container 97, 102
 - disposal lines 20, 162
- weigh system 42–43, 45
- weighing equipment 60
- weight
 - loss 52
 - shortage 72
- World Health Organization 13, 107, 109
- Xenobiotics 109
- yeast 88, 96, 100–101
 - extract 96, 100–101
- Yersinia* 30, 89
- Zero load indicator 76