HACCP & SCP

Hazard Analysis and Critical Control Point and Sanitation Control Procedures Training Curriculum

Trainer's Guide

Developed by the
Seafood HACCP Alliance
for Education and Training

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HACCP: Hazard Analysis and Critical Control Point Training Curriculum Trainer's Guide

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Seafood Train-the-Trainer Course

Battle Creek, MI
October 14-15, 2009

PURPOSE: Formal training course provided by the Seafood HACCP Alliance for Training and Education (SHA) held in company with the International Food Protection Training Institute (IFPTI) in Battle Creek, MI and the Association of Food & Drug Officials (AFDO). This training is specifically designed to prepare course trainers consistent with the established SHA protocol for 'approved' trainers to teach the SHA courses in both HACCP and Sanitation Control Procedures. This training assures the SHA courses will be provided in a standard and uniform manner consistent with the SHA protocol and regulatory mandates issued by the U. S. Food and Drug Administration. The instructors are members of the formal SHA Steering Committee and Editors Committee.

AGENDA:

Wednesday, October 14:

8:30 am – 9:00 am: Steve Otwell
Welcome, registration and introductions-Steve Otwell

9:00 am – 9:40 am: David Green
Chapter 1, Introduction to Course and HACCP (Green)
Chapter 2, Biological, Chemical and Physical (Green)

9:40 am – 10:20 am: Ken Gall and Lori Pivarnik
Chapter 3, Prerequisite Programs and Preliminary Steps (Gall)
Chapter 4, Commercial Processing Example (Pivarnik)

10:20am – 10:40 am: Break

10:40am – Noon: Michael Moody, Debra DeVlieger and Doris Hicks
Chapter 5, Principle 1-Hazard Analysis (Moody)
Chapter 6, Principle 2-Determine the Critical Control Points (DeVlieger)
Chapter 7, Principle 3-Establish Critical Limits (Hicks)

Noon – 1:20 pm: Lunch

1:20pm – 2:00 pm: Ken Gall and Debra DeVlieger
Chapter 8, Principle 4-Critical Control Point Monitoring (Gall)
Chapter 9, Principle 5-Corrective Actions (DeVlieger)

2:00 pm – 2:40 pm: <u>Doris Hicks and Tom Rippen</u>
Chapter 10, Principle 6-Verification Procedures (Hicks)
Chapter 11, Record-Keeping Procedures (Rippen)

2:40 pm – 3:10 pm: <u>Debra DeVlieger</u>
Chapter 12, Seafood HACCP Regulation

3:10 – 3:30pm: Break

3:30 – 4:00 pm: <u>Pamela Tom and Debra DeVlieger</u>
Chapter 13, Sources of Information on Preparing HACCP Plans and How to Use the Fish and Fishery Products Hazards and Controls Guide

4:00 pm – 4:30 pm: **<u>Ken Gall</u>**
Seafood HACCP Alliance Internet Training Course

<u>Thursday, October 15:</u>

8:30 am – 8:45 am: <u>Steve Otwell</u>
Administrative announcements

8:45 – 9:30 am: <u>Steve Otwell</u>
HACCP & SCP Training Protocol

9:30 – 9:45 am: Break

9:45 -11:30 am: <u>Karla Ruzicka</u>
Instructional Methodology Techniques (Adult learners) and effective conduct of practical exercises

11:30am – 12:30 pm: Lunch

12:30 pm – 4:00 pm: <u>Victor Garrido, Ken Gall, Lori Pivarnik & Tom Rippen</u>
TTT Sanitation Control Procedures

4:00 pm – 4:30 pm: <u>Steve Otwell</u>
Wrap-up and adjourn

Chapter 1: Introduction to Course and HACCP

Alliance seafood HACCP trainers are responsible for properly teaching HACCP principles and methods for implementation in a suitable learning environment. The purpose of this manual is to provide effective instructor techniques and approaches in accomplishing these tasks.

This Train-the-Trainer Guide is designed for trainers using the Seafood HACCP Alliance's course manual entitled, "HACCP: Hazard Analysis and Critical Control Point Training Curriculum" (fourth edition) and the U.S. Food and Drug Administration "Fish and Fisheries Products Hazards and Controls Guidance" (third edition) (also known as the FDA's Hazards Guide) in teaching the "Basic HACCP" and the "HACCP Segment 2" courses to fulfill the training requirement (21 CFR 123.10) of the Seafood HACCP Regulation (Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule 21 CFR 123 and 1240).

Students attending either the basic HACCP or Segment 2 course must have copies of both the Alliances's course manual and FDA's Hazards Guide throughout the training. In addition, students should be provided copies blank copies of hazard analysis sheets and HACCP Plan worksheets during the hands-on session during day three of the course. Trainers are encouraged to prepare and distribute class materials which support and reinforce the student's ability to comprehend and apply HACCP.

At a minimum, the audio visual materials in this course should include either the Seafood HACCP Alliance PowerPoint overheads or slides which follow the text. The PowerPoint materials can be downloaded from the web at: http://seafood.ucdavis.edu/haccp/training/training.htm . A flip chart, blackboard or overhead transparency should be available during the entire course. During the hands-on practical of day 3 (Segment 2) in developing a HACCP plan, an overhead projector should be available for the participants to share how they developed their hazard analysis and HACCP plans. Instructors should follow the course as outlined and teach the materials provided in the course manual. It may be useful to show videos, slides or provide demonstrations relative to the course but not included in the actual course curriculum. However, such extra curricular activities should be presented during lunch breaks or at times prior to or after the official class modules.

Training is more effective when the trainer discusses examples that participants can relate to their products. When possible, expand on the examples given in this guide. Engage a dialogue by asking participants to identify examples in their work situation.

The latest version of the Association of Food and Drug Officials and Seafood HACCP Alliance (AFDO/Alliance) HACCP and SCP training protocol, domestic and international course registration forms and training schedule are available on the web at: http://www.afdo.org/Training/HACCP/Seafood/Instructors.cfm

PLANNING AND INTRODUCING THE COURSE

The following are preliminary considerations for "setting the stage" for successful classroom instruction. All trainers are strongly encouraged to implement them.

Before the class begins:

1. Select a classroom setting that is conducive for learning. Consider the size of the room, acoustics, distractions (outside noises, interference from competing activities, etc.), desks (chairs and desks are essential), traffic, parking, accessibility for the disabled, air conditioning, ventilation, break and restroom areas, lighting (both for lighted situations and dim light situations for showing of presentations) security of the room for overnight storing of equipment, manuals, etc.
2. Break-out rooms for day 3 (Segment 2) should not create interference among the groups.
3. Provide best routes and maps to the site and other information which may be needed by the students prior to the start of the course. In some cases providing hotel information close to the training area could be useful.
4. Avoid giving an impression of not being prepared or ready for the class. Test out all audio/video equipment prior to the start of the class and have it set up and working. As students arrive for the first day of the course or Segment 2, have a system in place to for student sign-in, distribution of manuals (Basic Course), and finding a seat. Be prepared for students who arrive extremely early and others who may arrive late.

Convening the Class:

1. The manner in which you begin the class may set the tone for the entire course. Begin the class at the announced time and introduce yourself and accompanying instructors. Before or after the introductory remarks, the students can be asked to introduce themselves and briefly describe their reasons for attending the course.. To help the trainer and students become better acquainted with each other, provide paper tent name cards (or a blank 8-1/2 x 11" piece of paper folded lengthwise into thirds) so students can write names on the paper tent (or middle panel of the paper) and display on their desk. .
2. Your introductory remarks should include logistic details such as location of restrooms, suggested places to eat during lunch (a restaurant list would be helpful), emergency exit information in the event of fire or evacuation, etc.
3. Ask students to turn off cell phones and pagers but also inform them that there will be time to make calls during breaks and at lunch. (If you have a cell phone, use yours as an example in turning it off as you remind the class to turn their phone and pagers in the off mode.)
4. Make sure all students have the training manuals. This is a good time to explain the purpose of the class (meet the training requirements of 21 CFR 123). It is also advisable to explain the definition of a seafood processor and processing as

defined in 21 CFR 123 and exemptions (21 CFR 123.3 (k)(2)). Following this discussion, ask if there are any questions concerning the training and who must attend.

YOU ARE NOW READY TO TEACH HACCP!

In chapter one you are expected to provide an overview of the course to the class. Give student responsibilities including attendance and participation. Review the format of the class and how to use the curriculum manual. Cover the meaning and importance of HACCP as described in the manual. You will find that the students will particularly interested in the origins of HACCP and how the program has been successful in improving the food safety of the nation's food supply. Briefly introduce the seven principles of HACCP but do not dwell on the topic. Explain that each step will be covered in detail over the next three days. HACCP inspections versus traditional inspection should be discussed in this chapter. You will find that most processors have experienced a traditional inspection but may not be as familiar with the purposes of a HACCP inspection (food safety oriented). Before moving on to chapter 2, point out the list of definitions and acronyms at the end of the chapter for reference.

Chapter 2: Hazards – Biological, Chemical and Physical

This chapter is an introduction and background on food safety hazard that can be found in seafood products. Following the initial course introduction, this chapter also provides the instructor with the opportunity to begin the engagement and involvement of the course participants. The time allotment for this chapter is the longest in the course, other than the review of the seafood HACCP regulation itself.

There are many opportunities for the instructor to ask questions and receive answers from the students – begin with simple examples of hazards and ask related questions. Upon completion of the chapter, the participants should be able to differentiate specific hazards and GMP issues, and to identify characteristics of the three hazards (biological, chemical and physical) which apply to their operation.

Key Teaching Points:

1. Introduce the three classes of hazards (biological, chemical and physical) and how they differ from each other.

2. Define the concept of a hazard, and emphasize the difference between hazards under HACCP and conditions not directly related to the safety of the food (sanitation concerns to be covered by GMPs).

3. Discuss how the hazards occur in the environment, factors which contribute to their role as a hazard, and control methods to render the product safe.

4. Introduce the types of biological hazards (bacteria, viruses and parasites). Emphasize microorganism growth requirements, and use common examples. This concept is more important than covering each organism in detail or memorizing the different pathogens. Explain reproduction factors in simple terms, and note difference between pathogens and spoilage organisms. Discuss food borne illness symptoms, and methods to control microorganisms. This section allows for liberal use of common examples that can lead to discussion of specific instances from the instructor's experience.

5. Introduce the three categories of chemical hazards (i.e. naturally occurring allergens, intentionally added, and unintentionally added or incidentally added). Give examples of chemicals, both in the text and listed in Table B at the end of the chapter. Introduce sulfite as a hazard, as it will be used in the commercial processing example throughout the course. Identify and link chemical sources and practices that connect the hazard to the food product. Discuss why the examples are a hazard. Emphasize particularly histamine and ciguatera fish poisoning, and other potential examples common to seafood processing sectors in your area and participants.

6. Introduce physical hazards. Give examples of materials that may be physical hazards and describe the potential harm that may result and the control methods. This section is a good opportunity for class discussion, while introducing and discussing the

concept of ambiguous issues between hazard and quality or sanitation. Ask the class to consider bones in certain products (ie raw fillets and canned tuna) and shell pieces. Safety? Quality?

7. Discuss the Appendix 3 - Hazards Found in Seafood.

Chapter 3: Prerequisite Programs and Preliminary Steps

Although the Alliance course is primarily focused on HACCP, experience has shown that supplemental information on prerequisite programs and sanitation is helpful and beneficial for most students. Chapter 3 provides an opportunity for you to supplement the existing materials in the HACCP course curriculum to ensure that students understand these basic and important concepts. If the enhancements described below are utilized, you will need to prepare the appropriate materials prior to the class, and you may need to schedule an additional 15-30 minutes for this chapter in your agenda. Inform students that an additional one-day Alliance Sanitation Control Procedures course is available.

At a minimum, students should understand the relationship between GMPs, SSOPs and HACCP, and that the FDA Seafood HACCP regulation requires monitoring of eight areas of sanitation. You can supplement basic course materials to increase the students' understanding of sanitation/GMP requirements by guiding them through various examples outlined in the teaching points to demonstrate these concepts. You must make the transition from discussions of prerequisite programs to the process of developing a HACCP plan. The preliminary steps are the first steps that must be completed before applying the seven HACCP principles to develop a HACCP plan. Describe each of these "preparatory or information gathering" steps. A simple example of a small firm's preliminary step results could be used to illustrate this process.

Teaching Aids

1. Suggestions for supplemental visuals include:
    - A supplemental overhead of a pyramid diagram with GMPs and SSOPs as the base or foundation and HACCP at the apex (e.g. overhead I-9 from the Alliance SCP course)
    - A supplemental overhead that lists basic areas covered in the GMPs such as: personnel hygiene and disease control; buildings and facilities, sanitary operations, equipment, and production and process controls.
    - A supplemental overhead with the example in Key Teaching Point Part A #6 to describe the difference between GMPs and SSOPs that includes the elements in an SSOP (what, how, when and who).
    - Overhead I-12 from Alliance SCP course to contrast sanitation and HACCP controls (optional)
    - A supplemental overhead and handouts of the Daily Sanitation Monitoring form from the Alliance Encore Course Manual. (optional)
    - A supplemental overhead listing other common prerequisite procedures that may be needed such as: product specifications, equipment controls, recall procedures etc.
    - A supplemental overhead and handouts of Species List worksheet from the Alliance Encore Course Manual or other tools to help complete the second and third preliminary steps to describe how products are stored and distributed, and their intended use. (optional)

2. Appendix VI: Current Good Manufacturing Practices regulation in the HACCP training curriculum.

Key Teaching Points

Part A - Prerequisite Programs

1. Prerequisite programs must be in place to establish the sanitary conditions in the processing or food handling facility that are necessary for the safe handling or processing of food. These conditions are necessary to allow HACCP to do its job of focusing on specific food safety hazards associated with your products or process.

2. The Good Manufacturing Practice or "GMP" regulation describes what conditions and procedures are necessary for the safe handling or processing of food. Inform students that Appendix VI in the HACCP training curriculum contains a copy of the GMP regulation.

3. Review the areas covered in GMPs such as: personnel hygiene and disease control, buildings and facilities, sanitary operations, equipment, and production and process controls.

4. Describe the relationship between GMPs (which generally describes what conditions and procedures must be in place) and SSOPs (which specifically describe the procedures your firm uses to ensure that the conditions and procedures in the GMPs are adequately in place.

5. Describe what elements should be included in an SSOP including:
   What procedure will be used;
   How the procedure is conducted in your plant;
   When these activities occur; and
   Who is responsible for conducting them and supervising or monitoring them.

6. Give one or two examples of a "condition" specified in the GMP regulation and an "SSOP" outlining the procedures that a firm might use to meet that condition. For example, the GMPs state "no pests shall be allowed in any area of a food plant." A firm's SSOP might describe what pest control company they use and what specific activities the pest control company is expected to routinely and periodically conduct. The SSOP should also describe who monitors the pest company's performance, who monitors daily conditions to ensure that no pests are present, and what should be done if pests are found.

7. Emphasize that there is an additional new requirement in the FDA Seafood HACCP regulation to monitor eight areas of sanitation and review a list of each of these areas. Be sure that students understand that they now must monitor and keep a record of monitoring results for each of these eight areas in their plant even if they do not need a HACCP plan.

8. Review an overhead of the Daily Sanitation Monitoring form from the Alliance Encore course manual as an example of how to meet this requirement.
9. Review and briefly describe other prerequisite programs that may be needed such as: product specifications, supplier controls, equipment controls, recall procedures, etc.

Key Teaching Points
Part B - Preliminary Steps in the Development of a HACCP Plan

1. Explain that before you learn about and begin applying the seven HACCP principles there are some activities that you must complete. These activities are designed to help you gather the information you need and be prepared to develop your HACCP plan.
2. Review preliminary steps needed to get human resources aligned to develop your HACCP plan:
    - Identify who will be on the team that develops your HACCP plan. Give examples of various types of people that can contribute to this process.
    - Identify who needs to be trained and complete training.
    - Work with management to get their commitment.
3. Gather the information necessary about your products, process, and customers to develop your HACCP plan:
    - Describe your food products and how they are distributed. (Give examples)
    - Identify the intended use and consumers of your food products. (Give examples)
    - Develop a flow diagram that describes how products move through your facility/process.
    - Verify that the flow diagram is accurate by following product through your facility/process.
4. Review an overhead of the Species List worksheet from the Alliance Encore course manual that can be used as a tool to help you gather the information in the first two bullets above. Note: This worksheet was designed to closely resemble the product categories used in the "Process Related Hazards" Table 3-3 in the FDA's Fish and Fishery Products Hazards and Controls Guidance. Using this example now can help students avoid confusion when they use this reference later to conduct a hazard analysis.
5. Review an overhead of a simple flow diagram from core materials and emphasize the need to be sure that it accurately represents all potential steps for all products in your process.

6. Review an example of a simple firm (representative of your area if possible) with a simple flow diagram and only one or two products or product types to illustrate how they completed their preliminary steps as an optional discussion to reinforce these concepts.

References

- Seafood HACCP Alliance. 1999. Seafood HACCP Encore Course Manual, 68 pages. Web site: http://seafood.ucdavis.edu/haccp/encore%20manual2.pdf
- Seafood HACCP Alliance. 2001. Sanitation control Procedures for Processing Fish and Fishery Products Manual. Web Site: http://nsgl.gso.uri.edu/flsgp/flsgpe00001/flsgpe00001index.html
- FDA. 2001. Fish and Fishery Products Hazards and Controls Guidance, 3rd ed., Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Seafood, Washington, DC. Web site: http://www.cfsan.fda.gov/~comm/haccp4.html

Chapter 4: Commercial Processing Example: IQF Cooked Shrimp

This chapter introduces students to the fictitious firm, ABC Shrimp Co., that will be used as the example in each subsequent chapter to demonstrate the process of applying each HACCP principle to develop a HACCP plan.

No overheads or slides are provided for this chapter in the course materials. Trainers may find it useful to create overheads of the ABC Shrimp Company's process flow diagram (Figure 1 in Chapter 4 of the HACCP training curriculum) and sanitation control records (Tables 2 and 3 of the HACCP training curriculum).

Teaching Points

Part A - Process Description and Preliminary Steps

1. Provide an overview of ABC Shrimp's process flow diagram to introduce the overall process. In summary there are 1) two different types of raw product materials and packaging materials, 2) the product moves through a series of automated steps to convert it to a peeled and de-veined form; and, 3) the product is cooked, cooled, frozen and packaged.

2. Fresh raw shrimp are commonly treated with sulfites to prevent the oxidation of shell pigments from forming a quality defect known as "black spot." Mention that the ABC Shrimp Co. has quality and inventory control procedures for incoming product plus specific specifications regarding sulfites for frozen shrimp.

5. Briefly describe the next six steps (thawing, size grader, peeling, razor slide, tumbler/de-veiner, and conveyor/cull table cover) which a rapid automated process designed to convert shell-on shrimp to a peeled and de-veined product form. Note that there is a storage step in which all product converted to the peeled and de-veined form is collected and stored before moving on to the next step of the process.

6. The cooking step description is important. Note that steam is the cooking medium, and the cooker design ensures uniform heating. Emphasize that cooking time and temperature have already been established based on studies conducted on the specific cooker used in this process.

7. Note that there is a series of four (shuffler used to cool the product, cull table for quality control, a continuous spiral freezer, and glazing station) rapid automated steps that follow cooking.

8. Note that the finished product is packed in pre-labeled bags and that production codes and lot numbers are assigned at this step.

9. Explain that based on this process, the ABC Shrimp Co.'s product is defined as a "ready-to-eat, cooked, peeled and de-veined shrimp that is stored and distributed frozen, and intended for the general public." (Preliminary steps 2 and 3)

Key Teaching Points
Part B – The ABC Shrimp Co.'s SSOP and Prerequisite Programs

1. Table 1 contains a narrative description of the ABC Shrimp Co.'s Sanitation Standard Operating Procedures for the eight areas of sanitation covered in the FDA Seafood HACCP regulation.
2. It is not necessary to thoroughly describe each SSOP (ask your students to read this information as a homework assignment). However, try to emphasize the following points in describing the ABC Shrimp Co.'s SSOP format for each of the eight key sanitation conditions in the FDA Seafood HACCP regulation:

   Part 1. Controls and Monitoring – Describe what procedures are used to ensure that each sanitation condition is adequate and how you will monitor on a routine and/or periodic basis to ensure that conditions are acceptable. The ABC Shrimp Co. has eight different items in their SSOP to ensure compliance with the eight key sanitation conditions in the FDA regulation.

   Part 2. Corrections – Describes what will be done if routine monitoring shows that a deficiency exists for each of the control procedures listed.

   Part 3. Records – The records that will be kept to demonstrate monitoring results are listed.

   This format is used for:
   1. Water safety (water source and protection from contamination by cross connections).
   2. Condition and cleanliness of food contact surfaces are acceptable.
   3. Prevention of cross contamination (includes training, employee practices and facility).
   4. Maintenance of hand washing, sanitation and toilet facilities.
   5. Protection of food, food packaging and food contact surfaces from adulteration.
   6. Labeling, storage and use of toxic compounds.
   7. Employee health.
   8. Pest control.
3. Briefly review the ABC Shrimp Co.'s sanitation control records emphasizing the following:
   - The FDA Seafood HACCP regulation requires that you monitor, take, and document corrective actions for eight areas of sanitation.
   - This form is only an example of one company's strategy to meet this requirement. It is unlikely that this form can be used in your firm's unique circumstances.

- Remind students that there are other sample forms e.g. The Encore Course Manual form introduced in the previous chapter.
- Note that the monitoring form needs a title, the company's name and date. It also requires that you record your actual observation (e.g. ppm of chlorine), the time of the observation, and the name or initials of the person making the observation. Unlike HACCP records, sanitation records do not have to be reviewed by a "trained" individual although it is a good idea.
- In this example, the ABC Shrimp Co. is using one form for both daily and monthly activities. Other examples use one form for daily monitoring and another for monthly monitoring.

Reference

Seafood HACCP Alliance. 1999. Seafood HACCP Encore Course Manual, 68 pages. Web site: http://seafood.ucdavis.edu/haccp/encore%20manual2.pdf

Chapter 5: Principle 1: Hazard Analysis

Learning Objective:

Visual Aids:

- Distribute blank "Hazard Analysis Worksheets" for explanation, class referral, and notes.
- Use a transparency of the blank hazard analysis form to demonstrate how to complete the form or some other methods so that students can feel comfortable working with the form.
- FDA's Fish and Fisheries Products Hazards & Controls Guidance should be introduced at the conclusion of the hazards identification exercise.

Teaching Points:

1. This first principle of HACCP may be the most difficult to accomplish. Identifying all safety related hazards and keeping current on emerging hazards is challenging and requires effort. If all hazards can be successfully identified, then the remaining HACCP steps (principles) can be logically approached and completed.

2. All hazards must be food safety hazards. Students new to HACCP have a tendency to confuse food quality with food safety. Done properly, this exercise will greatly enforce the differences and focus on true food safety issues.

3. Distribute the blank Hazard Analysis Worksheets to the class. Have students refer to the worksheets during the instruction. Explain that the hazard analysis form is a tool to develop the HACCP plan and is NOT required by regulation to be released for inspectional purposes; however, processors may share this information with inspectors at their own discretion. Review each column and explain that each processing step, in order of processing, should be placed in one of the blocks in column one. This is a good time to review the three categories of hazards (biological, chemical and physical) as noted in column two.

4. Class participation with a hazards identification practical exercise is an extremely useful learning tool. Encourage all students to participate in identifying hazards. The instructor could use the shrimp example in the book or select another seafood product for this exercise. The receiving step is generally enough to demonstrate the hazard analysis process. Without referring to the shrimp example at the end of the chapter, have the students think of possible hazards associated with fresh shrimp and list them on a flip chart, overhead or black board. Let them go through the exercise of identifying possible hazards among the three categories. Do not discourage any suggested hazards; list all contributions. Do not suggest possible hazards for them; let the students figure them out. Do not hurry the process. This exercise encourages student participation and importantly, makes them think in terms of HACCP. Then using the bullet points from Overhead 5 (Hazard Analysis), go through each suggested hazard to authenticate if it is a true safety hazard asking the following two

questions. (1) Is the hazard likely to occur? and (2) Is the hazard likely to result in an unacceptable risk to consumers? These questions will open up discussion. It is useful to scratch through suggested hazards determined not be a hazard and to circle those hazards determined to be safety concerns. Take time to explain decisions made. You will find that many of the hazards suggestions are sanitation or food quality issues and not food safety. Use this as a teaching opportunity to explain differences between sanitation and safety hazards. You will find that the long list of ten or more hazards originally suggested has been reduced down to just one or two in most cases. At this point have students list the hazards on their hazards analysis form for the first processing step, and proceed to complete columns three and four (without referring to the example at the end of the chapter). After completing the entries, compare the hazards identified in the exercise with the shrimp example hazards in the training curriculum. After completing this exercise, explain the purpose of the FDA's Fish and Fishery Products Hazards and Controls Guidance and how it should be used in the hazard analysis process.

5. For every hazard identified, there must be an effective control measure (column five). Using a board, a blank transparency, or flip chart, write the formula: **Hazard = Control Measure**. Referring to this formula, discuss some examples of hazards and control measures. Some of the examples such as temperature, water activity, pH, etc. in the training curriculum are worth noting, especially those relating to seafood products most familiar with the students in the audience.

6. Review the IQF Cooked Shrimp Hazard Analysis worksheet example in the training curriculum.

Explain that hazards identified in column six are significant hazards and are the basis for the resulting HACCP plan.

Chapter 6: Principle 2: Determine the Critical Control Points

Learning Objective:

Visual Aids:
Use the hazard analysis worksheet transparency that was used in Chapter 5 and complete the question (Is this step a critical control point? Yes/No) in column six during this discussion. Students will need a hazard analysis form which may have been distributed during the previous presentation of Chapter 5.

Optional: Continue the hazard analysis identification practical from Chapter 5 with or without the use of the CCP decision tree.

Teaching Points

1. For every significant hazard that is identified during the hazard analysis, there will be at least one, and sometimes more points – or steps in the process, where the hazard will be controlled.

Clearly define "Critical Control Point" and make sure the students understand that a CCP is a point or step in the process where control is applied. The CCP is always a step (in the process) which is always listed on the hazard analysis. To avoid having students think of CCP's as only temperature and time, ask the class to provide other examples of CCPs.

2. Hazards can be controlled by:
   - prevention,
   - elimination, or
   - reduction to an acceptable level.

   Give examples that are in the training curriculum, but expand on those examples if possible. Alternatively ask the students if they can identify examples in each category.

3. Distinguish between CCP vs. Control Point and emphasize that CCP's are only assigned as those points in the process where control of a food safety hazard is applied. Discuss keeping things simple, and including only CCP's in the HACCP plan.

4. Introduce the CCP decision tree and explain that students could use it to finish their hazard analysis and identify the CCP's for the shrimp example. Emphasize that it is only ONE tool that can be used to help identify CCP's.

Chapter 7: Principle 3: Establish Critical Limits

The establishment of critical limits is one of the most important steps of the HACCP principles. While the chapter is relatively brief, substantial time should be devoted to this topic. The instruction becomes more effective when class participants become actively involved in the class presentation.

Key Teaching Points

1. It is important that the implications in selecting a critical limit be understood. In many instances, firms have established critical limits based on average parameters for a specific unit operation. When the established critical limit is exceeded, which happens occasionally during the year, a corrective action must be implemented. The need to implement the corrective action would have been avoided if a critical limit (based on a reasonable variation that did not compromise product safety) was established.

2. It is important that critical limits be established with respect to some scientific basis. If *Staphylococcus aureus* is an anticipated hazard for a unit operation, then the critical limit must be established with reference to the U. S. Department of Agriculture pathogen growth model, or some other reference appropriate for establishing the critical limit time and temperature of the operation.

3. Processors tend not to devote sufficient time to developing critical limits. A certain parameter may be established as a critical limit but that limit may reflect only 99 percent of the normal variation at that specific unit operation. A thorough review of the operation would have identified the 1 percent variation that was overlooked.

4. Too often a critical limit is established when it should be an operational limit. There is also a failure by firms to establish an operational limit for many unit operations to prevent exceeding a critical limit and thereby having to implement an appropriate corrective action. Many individuals have difficulty knowing exactly how to include an operational limit on a record or how to adequately transmit that information to their employees.

5. In discussing the establishment of critical limits, a discussion on the ABC Shrimp Co. model should be supplemented with information on the type of product or products the participants produce. Discussion on this chapter has always been more effective when participants can relate critical limits to their specific unit operations or products.

6. It is important to stress that all critical limits be established with reference to the most recent (currently the third edition) of the FDA's Fish and Fishery Products Hazards and Controls Guidance.

7. A recommendation should be made to participants that the establishment of critical limits that fail to represent actual information or are established without adequate scientific basis will result in some type of health regulatory agency response or a customer concern. In some instances, customer concerns are received from an indirect, rather than direct, customer. For example, a distributor may sell to a military food system and the U. S. Army Veterinary Corps will then inspect the processor.

References

- FDA. 2001. Fish and Fishery Products Hazards and Controls Guidance, 3rd ed., Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Seafood, Washington, DC. Web site: http://vm.cfsan.fda.gov/~comm/haccp4.html
- US Department of Agriculture Pathogen Modeling Program web site: http://ars.usda.gov/Services/docs.htm?docid=6786

Chapter 8: Principle 4: Critical Control Point Monitoring

This chapter offers an interesting opportunity for students and teachers to engage in technical conversation relative to obtaining processing data. Unlike some aspects of HACCP, most seafood processors have some experience in monitoring with instruments. In addition, most are interested in the topic. There are many companies that offer instruments, software and similar systems designed specifically for HACCP data acquisition. Make the most of the situation and get students involved. The following recommendations generally help.

Visual Aids:

A static display of some commonly used portable monitoring equipment such as digital thermometers, water activity meters, timing devices, pH meters, etc. is an attention getter and educates processors on what is available. A simple demonstration using some equipment is interesting if time permits. Students will generally ask where monitoring equipment can be purchased. Providing sources for vendor information may be useful. To avoid conflict of interest, however, do not recommend a particular brand or company. This decision rest with the processor.

Key Teaching Points:

1. Stress to students that the only way to ensure that CCPs are meeting critical limits is by accurately monitoring. These data, in turn, should be used to generate your HACCP records. Sticking one's finger into a cooking vessel to estimate temperature may have been sufficient many years ago but that method will not pass muster today. Monitoring ACCURACY is the key word here. Importantly, monitoring will warn of an impending deviation before it happens. Emphasize that monitoring is only as good as the accuracy of the equipment that is performing the monitoring. This is a good place to relay some experiences or examples of trying to process with an inaccurate monitoring device and the potential losses that could occur.

2. Point out that required monitoring HACCP plan information uses four of the ten columns. Review each of the columns and spend time in open discussion while on Overhead 5 (HACCP Plan Form). Since the information needed for the columns seems simple, many students have a tendency to fill out the HACCP form monitoring information casually without fully understanding the significance of the information. Each column was put there for a purpose and not just to take up space.

   Under the heading, “How Critical Limits and Control Measures will be Monitored,” the examples used provide an opportunity for further discussion. For example, there are computer software packages available that permit a processor to monitor F-values when pasteurizing crab meat. This type of monitoring is useful when can sizes vary. In addition, water activity measurements give discussion opportunities for optional monitoring techniques.

3. Although monitoring sometimes involves subjective measurements such as visual inspections, the more complex monitoring systems require instrumentation. Most seafood processors are extremely interested in monitoring equipment demonstrations. This chapter provides a "teachable moment" to provide hands-on experiences in using monitoring equipment. For example, displaying and demonstrating the advantages and disadvantages of the varying types of thermometers (electronic, digital, metal coil, etc.) is useful. While the use of computer records as an option to manual record keeping is briefly discussed in another chapter, it is useful to discuss monitoring CCPs using computer technology in data acquisition.

4. Instructors tend not to discuss the importance of monitoring instrument accuracy and its relationship to establishing critical limits. The critical limit should always be higher at least as much as the upper or lower accuracy variance of the instrument than the target critical limit. See the example in the training curriculum.

5. Monitoring frequency always raises many questions. Carefully explain continuous vs. non-continuous monitoring and the desire to have continuous monitoring where practical. Although confidence in monitoring equipment and company risk associated with monitoring frequency are primary considerations, regulatory agencies expect companies to monitor frequently enough to take the necessary corrective actions in the event of a deviation. Process frequency and other factors may also have a bearing on monitoring..

Chapter 9: Principle 5: Corrective Actions

This chapter is challenging to teach. The concept is new to many processors, especially the requirement to make corrective action records. It is important that processors understand that corrective actions must be thought out prior to the deviation occurring.

Visual Aids:

Flip chart, erasable board or transparent overhead is useful in conducting a class exercise in developing a corrective action record. These same visual aids could be used for a class activity to use the "If/Then" principle.

Key Teaching Points:

Make sure students have an appreciation of both short-term and long-term fixes for process deviations. Emphasize that a long-term fix may be redoing or modifying the HACCP plan.

1. When monitoring shows that a critical limit deviation has occurred, a corrective action **must** be taken. Firms must be sure that any product with a food safety hazard is not distributed. Firms also need to restore control of the process, as soon as possible.

2. Emphasize the components of a corrective action:
   - Correcting the problem that caused the deviation using both short-term and long term solutions, if necessary.
   - Identifying the product produced during the critical limit deviation (monitoring records will show when products were last produced without exceeding the critical limit.)
   - Determining if a food safety hazard exists. If an expert's evaluation or testing shows that no hazard exists, the product may be released. Both the critical limit deviation and corrective action **must** be documented.
   - If a hazard exists or may exist, then determine if the product can be reworked or diverted to another safe use.
   - It the product cannot be reworked, reprocessed, or diverted to another use, then the product must be destroyed. This is usually expensive and is considered a last resort.
   - If the critical limit deviation occurs at a receiving CCP, then the product can be rejected.

3. All corrective action records shall include the following:
   - Product identification (e.g., product description, amount of product on hold).
   - Description of the critical limit deviation.
   - Corrective action taken and final disposition of the affected product. This is a critical learning objective. Take the time to make sure students understand proper

disposition of suspect product. This is a teachable moment and good time to encourage class participation.

- Date and time of the correction.
- Signature or initials of the individual responsible for taking the corrective action.
- Results of the safety evaluation (biological, physical, or chemical test results and /or results of expert evaluation) when necessary.

This is a good time to take the class though a record development process. Emphasize the required record information necessary to have an acceptable record.

4. Microbiological testing is usually not an appropriate corrective action measure, as there are numerous pathogens for which testing can be conducted, sample size would need to very large, and results can take days or longer.

5. Corrective action procedures ensure that unsafe product does not reach the end user and the problem that caused the critical limit deviation is corrected.

6. Deviations from operating limits, or at control points, do not result in formal HACCP corrective actions.

7. FDA does not require that firms have written corrective actions. When conducting an inspection if monitoring shows that a critical limit was exceeded FDA will look for the corrective action record.

8. If a company does not have a written corrective action plan there are four steps the company must follow. Emphasize the four steps outlined in the HACCP training curriculum or Module 9 for the Internet course.

9. Give examples of corrective actions. Explain what the IF/THEN format is. "IF a deviation occurs: Oysters not tagged properly at receiving. THEN corrective action: Reject oysters." Choose a chapter in the hazards guide and walk the audience through the IF/THEN scenario. Use the appropriate visual aids to get the whole class involved in the exercise.

10. There are many other examples available to use in the training curriculum and also in the Fish and Fishery Products Hazards and Controls Guidance. Step #16 of each chapter of the Guidance gives examples of corrective actions. For an example see page 244: "For each processing step where 'allergens/additives' is identified as a significant hazard on the HACCP plan form describe the procedures" that firms will use when the critical limit has not been met. Step #16 gives three examples of corrective actions that correspond to the control strategies examples discussed in Step #12 of the same chapter (Chapter 19 Allergens/Additives.)

11. The corrective action procedures are entered in column eight of the HACCP plan form.

12. The Guidance contains information to help you develop appropriate corrective actions. Other resources include advice from experts, testing laboratories or test kit manufacturers, equipment manufacturers, or other HACCP models.

References

- FDA. 2001. Fish and Fishery Products Hazards and Controls Guidance, 3rd ed., Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Seafood, Washington, DC. Web site: http://vm.cfsan.fda.gov/~comm/haccp4.html
- Gall, K. 2001. Seafood HACCP Alliance Internet Training Course. New York Sea Grant and Cornell University. Web site: http://seafood.ucdavis.edu/haccp/training/cornell.htm

Chapter 10: Principle 6: Verification Procedures

Key Teaching Points

1. Define verification and make the distinction between routine monitoring activities and validation.

2. Explain the four elements of verification (validation of the plan, CCP verification activities, HACCP system verification, and role of regulatory agencies).

3. Based on Overhead 8 (Validation Frequency), impress the point that validation of the plan occurs before the plan is actually implemented and that validation activities may be similar in scope and time commitment to the original HACCP plan development. Review the frequency and factors warranted in performing validation of the plan.

4. Explain that verification activities (calibration, calibration record review, targeted sampling and testing, and CCP record review) ensure that the control procedures used are properly functioning. Ask the class to identify types of monitoring equipment in their operation that needs to be calibrated. Have students make a note that examples of monitoring equipment are on page 85 of Chapter 8 of the training curriculum.

5. Under "Calibration Record Review" point out where on the HACCP plan (under the Cooker CCP, verification step). Then have students go to Chapter 11 and review the Equipment-Calibration Log example. Note that review of these records shall occur within a reasonable time after the records are made.

6. For CCP Record review point out that 1) two types of records are generated at each CCP (monitoring and corrective action), and 2) someone in a supervisory capacity needs to review the records within one week of the day that the records are made.

7. Point out that a system-wide verification of the HACCP plan should be yearly (at a minimum) or whenever there is a system failure or a significant change in the product or process. Review the four verification activities of the HACCP system.

8. Point out that reviewers of records are assessing that monitoring activities have been performed at the locations and frequencies specified in the HACCP plan, that corrective action have been performed whenever monitoring indicated deviation from critical limits and that equipment has been calibrated at the frequencies specified in the HACCP plan.

9. Discuss microbiological testing as a verification tool.

11. Explain the role of regulatory agencies in a HACCP system and identify the six procedures involved.

Chapter 11 Principle 7: Record-Keeping Procedures

Key Teaching Points

1. Identify the four categories of records that are kept as part of a HACCP system:
   1) HACCP-Plan Support Documents (includes sanitation monitoring and sanitation correction records),
   2) Monitoring Records,
   3) Corrective Action Records, and
   4) Verification Records (including importer verification).

2. Review the requirements of records. Records need to be accurate. Critical control point monitoring information shall contain the actual values and observations obtained during monitoring, provide documentation that critical limits have been met, and signed or initialed by the person doing the monitoring. Corrective actions shall be documented in records and require verification. The calibration of process-monitoring instruments, performing any periodic end-product and in-process testing shall be documented in (verification) records.

3. Review the general requirements which *all* HACCP records shall include (21 CFR 123.9a).

4) Review computerized records requirements. Computerized records are acceptable when controls are used to ensure that the records are authentic, accurate and protected against unauthorized changes.

5) Review record retention requirements. CCP monitoring and corrective action records shall be reviewed within one week of the day that the records are made. Reviews of verification tests (i.e., calibration of any process control instruments used at CCPs, periodic end-product or in-processing testing) shall be reviewed within a reasonable time after the records are made.

6) Explain what the reviewer should be assessing during a record review.

7) Review record retention principles (21 CFR 123.9b).

8) Note that all required records, plans and procedures shall be available for official review and copying at reasonable times.

9) Review record requirements for imported products.

10) Review and clarify HACCP record and plan samples (p. 116 - 126) in the book with the class.

Teaching Aids

- To illustrate Key Teaching Point create an animated PowerPoint slide to highlight the entries as the required elements of the HACCP records are discussed. (Minimize this technique for impact and use the technique to foster discussion or class participation.)
- The HACCP plan in Chapter 10 (p. 108-109) can be used for group discussion in completing the "records" column (10) of Chapter 11 (p. 125-126).
- To guide the student in locating information related to records throughout the book and HACCP regulation, distribute "Supplemental Information Pertaining to Records in the HACCP Training Curriculum"
- To introduce and emphasize the types of records required, prepare and display labeled folders with examples of records (HACCP Plan, support documentation, CCP monitoring records, corrective action records, verification activities records, SSOP monitoring and correction records).
- Print examples of records lacking the "reviewed by and date" entries (p. 117-120 overheads 7, 10 -12). Then use a rubber stamp (4-1/4 x 1" with minimum of ½" between reviewer and date lines; Arial bold16 pt . font) and ink pad that has the imprint of "reviewer's signature and date" and stamp the form to emphasize the point that required records need to be reviewed and signed. For the HACCP plan, flip it over and stamp it and emphasize that the HACCP plan needs to be reviewed annually, upon modification, and upon reassessment of the HACCP plan.
- In addition to the HACCP curriculum record examples (p. 116-124), sample record forms are available at:
  http://seafood.ucdavis.edu/haccp/monitoring/monitoring.htm
  1. Blue Crab Can Seam Evaluation Record
  2. Corrective Action Record
  3. Crabmeat Picking Time Record
  4. Pasteurized Crabmeat Cooler Temperature Record
  5. Pasteurization Record
  6. Pouch Integrity and Thickness Record
  7. Thermometer Calibration Record

Supplemental Information Pertaining to Records in the HACCP Training Curriculum

Ch. 3: Prerequisite Program (re: sanitation record requirements, top paragraph, last sentence, overhead 4, and first sentence after overhead 4) p. 29 and page 139 (overheads 23 - 24)

Ch. 9: Corrective Action record requirements p. 95

Ch. 10: Record review p. 103-107

Ch. 11: Principle 7: Record-Keeping Procedures 111-126

- Examples of records p. 116-124
- ABC Shrimp HACCP plan form p. 125-126

Ch. 12: Seafood HACCP regulation p. 132-144 (Overheads: 11-13, 18-24, 27, 35)

Appendix 1: FDA's Seafood HACCP Rule p. 155-170

21 CFR §123.6b and c (7) HACCP plan and record keeping
21 CFR §123.7d Corrective action records
21 CFR §123.8d Verification records
21 CFR §123.9 Records
21 CFR §123.11c Sanitation Control Procedures
21 CFR §123.12c Special Requirements for Imported Products, Records
21 CFR §123.28c Raw molluscan shellfish
21 CFR §123.28d Shucked molluscan shellfish

Chapter 12: The Seafood HACCP Regulation

You may wish to include display or distribution copies of the following as visual aids in your presentation: the Federal Register document 21 CFR Parts 123 and 1240, the Seafood HACCP Alliance's Sanitation Control Procedures Manual (when discussing the section on Sanitation Control Procedures 123.11), the Current GMP regulations, and the FDA's "HACCP Regulation for Fish and Fishery Products, Questions and Answers, Issue Three.".

Key Teaching Points

1. Have the students turn to Appendix 1 and show them that their training manual contains the full Seafood HACCP Regulation. Advise students that they can easily search through the Seafood HACCP Regulation with the "find" feature (usually located under "edit" of their browser).

2. Give a brief history of the regulation. Refer them to the preamble in the Federal Register that discusses the factual basis for the regulation.

3. Explain that Chapter 12 highlights the key areas (i.e., definitions and requirements) of the seafood HACCP regulation.

4. Explain that the regulation has three main parts:
   - General Provisions: which apply to everyone,
     AND two sections that discuss specific requirements for two industries:
   - Smoked and Smoke-Flavored Fishery Products, and
   - Raw Molluscan Shellfish.

5. Emphasize the definitions for key term so that industry attendees will understand whether their product and company are covered by the regulation:
   - Fish
   - Fishery Product
   - Importer
   - Processor
   - Processing
   - Shall
   - Should

6. Review the steps to performing a hazard analysis, and discuss the term "reasonably likely to occur." Emphasize that this is a preventive program and that illnesses need not have been reported in the past in order to establish that a hazard is reasonably likely to occur and that controls are needed. Discuss that processors must perform a hazard analysis, but that a written hazard analysis is not required. Point out that it may be useful to have a written hazard analysis if disagreements with regulatory authorities are encountered.

7. Discuss requirements of the HACCP plan and relate them to the previous chapters on the seven principles of HACCP.

8. Discuss the need for and significance of signing the HACCP plan.

9. Discuss the relationship between FDA's Low Acid Canned Foods and Acidified Foods Regulations (21 CFR Parts 113 and 114) to the Seafood HACCP regulation. Note that processors that have to comply with the requirements in those regulations do not need to address *Clostridium botulinum* in their HACCP plans – However, other hazards that are reasonably likely to occur in those products must be addressed in a HACCP plan. Give examples!

10. Describe the legal basis for the regulation and explain 402(a)(4). Discuss the fact that FDA does not have to have a violative physical sample to determine adulteration. Tell students that, under 402(a)(4), if a firm does not have a HACCP plan when one is needed to control a hazard, the product can be deemed adulterated and subject to regulatory action.

11. Discuss the relationship between FDA's Part 110 GMP's and the Sanitation monitoring requirements of the regulation. Explain how they compliment each other and remind students that sanitation is a prerequisite program that must be followed even if there is no need for a HACCP plan. Tell the students that more information on GMP's and sanitation can be obtained from the Seafood HACCP Alliance's Sanitation Control Procedures course.

12. Explain that corrective actions must always have two parts – one to address the deviant product and the other is to correct the cause of the deviation. If one of the two elements is not addressed in the HACCP plan, an objectionable condition exists. Discuss "pre-determined" corrective action and the alternative – to follow the default corrective action plan outlined in the regulation.

13. Discuss verification and what is covered under periodic assessment vs. ongoing verification activities. Explain record review as it relates to the verification process.

14. Inform students of the records that are required by the regulation, what is required on each record, how long they should be retained and that FDA does have access to review and copy the required records.

15. Discuss FDA's recognition of the Alliance's "standardized curriculum" and how other training can meet the requirements of the regulation. Tell students what activities are to be performed by a trained individual.

16. Talk about the Sanitation Monitoring Requirements and their relationship to Part 110, the Current GMP's. Note the requirement for sanitation monitoring records. Note again that sanitation monitoring is required even if there is no need for a HACCP

plan. Note to students that implementation of sanitation monitoring is as important as implementation of the HACCP plan, especially in the production of ready-to-eat products.

17. Explain FDA's attempt to have a level playing field for both domestic and foreign processors. Tell students that three documents are required by importers:
    - Written verification procedures
    - Product specifications addressing biological, chemical and physical hazards
    - One or more affirmative steps as outlined in the regulations

18. Discuss the special requirements for processors of smoked and smoked-flavored products and how the product's history played a key part in this section of the regulation.

19. Discuss the special requirements for processors of RAW molluscan shellfish and how the product's history played a vital role in the development of this section of the regulation.

References

- FDA, 1995. Federal Register 60 FR 65095 December 18, 1995. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule. 21 CFR 123 and 1240. Part III, Regulation, pp. 65197-65202. Web site: http://vm.cfsan.fda.gov/~lrd/searule3.html
- FDA. 1999 HACCP Regulation for Fish and Fishery Products Questions and Answers for Guidance to Facilitate the Implementation of a HACCP System in Seafood Processing. Issue Three. Web site: http://vm.cfsan.fda.gov/~dms/qa2haccp.html
- FDA. 2001 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. Web sites:
  http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr110_01.html (English)
  http://vm.cfsan.fda.gov/~lrd/scfr110.html (Spanish)
- Seafood HACCP Alliance. 2001. Sanitation Control Procedures for Processing Fish and Fishery Products Manual. Web Site:
  http://nsgl.gso.uri.edu/flsgp/flsgpe00001/flsgpe00001index.html (English)
  http://nsgl.gso.uri.edu/flsgp/flsgpe00003/flsgpe00003index.html (Spanish)

EXAMPLE ONLY

Importer Written Verification Procedures
(Including Determination of Compliance)

Your company (importer) Name:
Address:

Company (exporter) Name:
Address:

Product Description: Mahi Mahi

Product Specification and Affirmative Step – record review:

1. **Product Specification Completed for Mahi Mahi: YES NO**

2. **Affirmative Step Applied: Option B - obtaining a continuing certificate (from an appropriate foreign government inspection authority) certifying that the mahi mahi is or was processed in accordance with the requirements of the US Seafood HACCP regulation.**

    - **Certificate states the product name and attests to the fact that the mahi mahi was processed under HACCP and sanitation requirements outlined in 21 CFR Part 123: YES NO**

    - **Certificate is signed: YES NO**

    - **Expiration date is on the certificate: YES NO**

Reviewer:_____ Date:_____

EXAMPLE ONLY

EXAMPLE ONLY

Product Specifications

Company (importer) name:
Address:

Product name: **Mahi Mahi**

Product form: **H & G, Loins, Fresh, Frozen**

Intended use: Raw (as sashimi) or cooked

Potential Biological Hazards:

1. **Bacterial pathogens: Suppliers must adhere to strict sanitation and the sanitation monitoring requirements contained in FDA's Seafood HACCP regulation and assure its SOP's and GMP's minimize the occurrence of potentially harmful bacteria.**

Potential Chemical Hazards:

1. **Histamine: Certain species of finfish, such as mahi mahi, when subject to time-temperature abuse may develop harmful levels of histamine (sometimes called scombrotoxin). To ensure that harmful levels of histamine do not develop, mahi mahi sold to (Company Name) must be processed under a HACCP system with temperature controls in place from the time of harvest to the time the product is received by our company. Unless there is evidence (from data loggers, temperature recording devices, ice, etc) documenting proper in-transit temperature controls at receipt, the shipment will be rejected.**

2. **Histamine must not exceed 50 ppm according to FDA action levels.**

Potential Physical Hazards:

1. **None for this product**

EXAMPLE ONLY

Chapter 13
Sources of Information on Preparing HACCP Plans

Key Teaching Points

1. Describe how Chapter 13 is divided into two main parts (1. sources of information, and 2. how to use the FDA's "Fish and Fishery Products Hazards and Controls Guidance") for conducting a hazard analysis and developing a HACCP plan.

2. Review the key sources of information.

3. Discuss how the Seafood Discussion Group Mailing List can provide assistance and guidance on seafood HACCP issues.

4. Explain how the Compendium of Fish and Fishery Processes, Hazards and Controls (http://seafood.ucdavis.edu/haccp/compendium/compend.htm) is a Seafood HACCP Alliance internet document designed to complement the FDA's Hazards and Controls Guidance and the HACCP training curriculum in developing a HACCP plan.

5. Note that the FDA's Fish and Fisheries Products Hazards and Controls Guidance, a primary tool for conducting a hazard analysis and developing a HACCP plan, is a non-binding source for identifying species and process related hazards in seafood.

6. Review the distinct features of the chapters and appendices of the Guidance.

7. Demonstrate how the steps in Chapter 2 of the Guidance can be followed to complete the hazard analysis and HACCP plan worksheets.

8. Remind the class that the HACCP plan needs to be signed and dated by either the most responsible individual onsite at the processing facility or by a higher level official of the processor.

9. Distribute blank hazard analysis and HACCP plan worksheets to the class. Based on the ABC Shrimp Co. example in the training curriculum, show how steps in the Guidance correspond to spaces and columns on the worksheets. If time permits, select a seafood product example and use the Guidance to review how to complete the forms.

10. Inform the class that in preparation for day three of the HACCP course their homework is to familiarize themselves with the steps in Chapter 2 of the Guidance for conducting a hazard analysis and developing a HACCP plan.

Table 1. How the Hazards Guide Steps Correspond to the Hazard Analysis Worksheet

Refer to Chapters 2, (Conducting a Hazard Analysis and Developing a HACCP Plan), 3, 4-21 and Appendices 3-6 of the FDA Hazards Guide to identify the corresponding step and instructions for completing the hazard analysis worksheet. You may choose other equivalent peer reviewed publications or control strategies that are different from the Hazards Guide provided that they assume an equivalent degree of safety of the product.

Firm Name: **Chapter 2, Step 1**		Product Description: **Chapter 2, Step 2**	
Firm Address: **Chapter 2, Step 1**		Method of Storage and Distribution: **Chapter 2, Step 3**	
		Intended Use and Consumer: **Chapter 2, Step 4**	

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/processing step	Identify potential hazards introduced, controlled or enhanced at this step (1)	Are any potential food-safety hazards significant? (Yes/No)	Justify your decisions for column 3.	What preventative measures can be applied to prevent the significant hazards?	Is this step a critical control point? (Yes/No)
Chapter 2: Step 6.	**Chapter 2,:Steps 7 and 8, and Chapter 3: Tables #3-1, 2, 3.**	**Chapter 2: Step 9 and Chapters 4-21: Steps 10 and 11.**	**Chapters 4-21: Steps 10 and 11.**	**Chapters 4-21: Steps 10 and 11.**	**Chapters 4-21, Step 12 and Appendix 3.**

Table 2. How the Hazards Guide Steps Correspond to the HACCP Plan Form

Refer to Chapters 2, (Conducting a Hazard Analysis and Developing a HACCP Plan), 3, 4-21 and Appendices 3-6 of the FDA Hazards Guide to identify the corresponding step and instructions for completing the HACCP plan form.

<table>
<tr><td colspan="4">Firm Name: Chapter 2, Step 1

Firm Address: Chapter 2, Step 1</td><td colspan="5">Product Description: Chapter 2, Step 2

Method of Storage and Distribution: Chapter 2, Step 3

Intended Use and Consumer: Chapter 2, Step 4</td></tr>
<tr><td rowspan="2">(1)
Critical Control Point</td><td rowspan="2">(2)
Significant Hazards</td><td rowspan="2">(3)
Critical Limits for each Preventive Measure</td><td colspan="4">Monitoring</td><td rowspan="2">(8)
Corrective Actions</td><td rowspan="2">(9)
Verification</td><td rowspan="2">(10)
Records</td></tr>
<tr><td>(4)
What</td><td>(5)
How</td><td>(6)
Frequency</td><td>(7)
Who</td></tr>
<tr><td>Chapter 2: Step 13</td><td>Chapter 2: Step 13</td><td>Chapters 4-21: Step 14.</td><td colspan="4">Chapters 4-21: Step 15.</td><td>Chapters 4-21: Step 16.</td><td>Chapters 4-21: Step 18.</td><td>Chapters 4-21: Step 17.</td></tr>
<tr><td colspan="11">Signature of Company Official: Chapter 2, Step 18. Date: Chapter 2, Step 18.</td></tr>
</table>

Teaching Aids

- Blank copies of the Hazard Analysis worksheet and HACCP plan form (to be used during the session on how to use the FDA Hazards Guide).
- Fish and Fisheries Products Hazards and Controls Guidance (FDA Hazards Guide).
- HACCP Training Curriculum
- Display samples of the publications mentioned in the curriculum and any additional relevant resources that will assist your participants in developing their HACCP plans.
- (Optional) Use Post-its to help students quickly refer to various chapters in the training curriculum and Hazards Guide when reviewing Hazard Analysis and HACCP Plan development steps.

Resources via the Internet

- Generic flow diagram, hazard analysis and HACCP plan worksheets are available as Word and PDF files: http://seafood.ucdavis.edu/seafoodhaccp.html#section2
- Guidance for Industry: Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/ucm071329.htm
- HACCP regulation for fish and fishery products questions and answers for guidance to facilitate the implementation of a HACCP system in seafood processing. 1999 http://vm.cfsan.fda.gov/~dms/qa2haccp.html
- Seafood HACCP Alliance Manuals:
  - HACCP: Hazard Analysis and Critical Control Point Training Curriculum (Fourth Edition, 2001), 288 p. http://nsgl.gso.uri.edu/flsgp/flsgpe01001.pdf (1.7 MB)
  - HACCP: Hazard Analysis and Critical Control Point Training Curriculum (In Spanish, Fourth Edition, 2004), 289 p. http://nsgl.gso.uri.edu/flsgp/flsgph04002.pdf (1.5 MB)
  - Sanitation Control Procedures for Processing Fish and Fishery Products (2000), 194 p. http://nsgl.gso.uri.edu/flsgp/flsgpe00001/flsgpe00001_full.pdf (10.7 MB)
  - Sanitation Control Procedures for Processing Fish and Fishery Products (In Spanish, 2003), 206 p. http://nsgl.gso.uri.edu/flsgp/flsgpe00003/flsgpe00003_full.pdf (8.1 MB)
  - Seafood HACCP Encore Course Manual (1999), 68 p. http://seafood.ucdavis.edu/haccp/encore%20manual2.pdf (270 KB)
- Seafood Imports List of Foreign Processors Approved by their Governments - The inspection authorities of some countries are issuing lists of processors that are in good standing with those authorities and are, according to the authorities, processing in accordance with the U.S. requirements. These lists, if regularly updated, may serve the same purpose as the issuance of "continuing" certificates by the foreign government inspection authority. Importers may consider purchasing from processors that are on such lists, and documenting that they are doing so, as one way of meeting their affirmative steps responsibility. http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/SeafoodHACCP/ucm118763.htm
- Sources of Information on Preparing HACCP Forms: http://seafood.ucdavis.edu/haccp/ch13sources.htm
- Training Resources: Food Safety, HACCP and Sanitation: http://seafood.ucdavis.edu/Pubs/99resources.htm

Sources of Information on Preparing HACCP Forms*

*Based on a revised version of Chapter 13 of the HACCP: Hazard Analysis and Critical Control Point Training Curriculum, 4th Edition, 2001. Developed by the National Seafood HACCP Alliance for Training and Education http://seafood.ucdavis.edu/haccp/ch13sources.htm .

Seafood Processors

Trade Associations
http://seafood.ucdavis.edu/organize/org-ass.htm

Consultants and Consulting Firms

University Sea Grant/Cooperative Extension
Sea Grant
http://seafood.ucdavis.edu/organize/org-sg.htm
Cooperative Extension
http://www.csrees.usda.gov/qlinks/partners/state_partners.html

Government Inspectors
U.S. Food and Drug Administration District Offices (ORA Field Directory)
http://www.fda.gov/ICECI/Inspections/IOM/ucm124008.htm
U.S. Department of Commerce, Seafood Inspection Program Offices
http://www.seafood.nmfs.noaa.gov/Regional_Offices.html

Buyers, Suppliers and Analytical Laboratories

PUBLICATIONS

US FDA Fish and Fishery Products Hazards and Controls Guide
http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm

FDA Bad Bug Book:
Foodborne Pathogenic Microorganisms and Natural Toxins Handbook
http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/default.htm

FDA Compliance Policy Guides (CPGs) and Import Alert
Compliance Policy Guidance Manual
http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm

FDA's Import Program
http://www.fda.gov/ForIndustry/ImportProgram/default.htm

FDA National Shellfish Sanitation Program (NSSP) Guide
http://www.issc.org/NSSP/Default.aspx

NOAA Seafood Inspection Program
NMFS HACCP Manual
http://seafood.nmfs.noaa.gov/manual.html
Publications provided by the NOAA Seafood Inspection Program
http://www.seafood.nmfs.noaa.gov/Publications.htm

U.S. Department of Agriculture (USDA) HACCP and Pathogen Reduction
http://www.fsis.usda.gov/Science/hazard_analysis_&_pathogen_reduction/index.asp

National Advisory Committee on Microbiological Criteria for Foods (NACMCF)
http://www.fsis.usda.gov/About_FSIS/NACMCF/index.asp

National Academies Press
Seafood Choices: Balancing Benefits and Risks (2007)
http://www.nap.edu/catalog.php?record_id=11762
Seafood Safety (1991)
http://www.nap.edu/books/0309043875/html/index.html

Centers for Disease Control and Prevention (CDC)
http://www.cdc.gov/
Morbidity and Mortality Weekly Report
http://www.cdc.gov/mmwr/

Codex Alimentarius (CODEX)
http://www.codexalimentarius.net/index_en.stm
Codex Alimentarius, Code of Practice for Fish and Fishery Products, First Edition (2009)
http://www.fao.org/docrep/011/a1553e/a1553e00.htm
Current Official Standards
http://www.codexalimentarius.net/standard_list.asp

Canadian Food Inspection Agency
Food Safety Enhancement Program
http://www.inspection.gc.ca/english/fssa/polstrat/haccp/haccpe.shtml

National Sea Grant Library
Digital HACCP Library
http://nsgd.gso.uri.edu/haccp.html

COMPUTER-ACCESSIBLE INFORMATION SOURCES

FDA's Home Page
http://www.fda.gov/
FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2004/2005
http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/SeafoodHACCP/ucm111059.htm

HACCP Regulation for Fish and Fishery Products Questions and Answers for guidance to Facilitate the Implementation of a HACCP System in Seafood Processing
http://vm.cfsan.fda.gov/~dms/qa2haccp.html

Regulatory Fish Encyclopedia
http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/RegulatoryFishEncyclopediaRFE/default.htm

Seafood HACCP
http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/SeafoodHACCP/default.htm

Seafood Information and Resources
http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/default.htm

AquaNIC – Aquaculture Network Information Center
http://aquanic.org/

USDA, Food Safety Information Center
Education and Training Materials Database
http://foodsafety.nal.usda.gov/fsic/fseddb/fseddbsearch.php

Seafood HACCP
http://foodsafety.nal.usda.gov/nal_display/index.php?info_center=16&tax_level=2&tax_subject=177&level3_id=0&level4_id=0&level5_id=0&topic_id=1148&&placement_default=0

Seafood Discussion Group (Mailing List)
http://seafood.ucdavis.edu/listserv/listinfo.htm

SeafoodNIC – Seafood Network Information Center
http://seafood.ucdavis.edu/

Compendium of Fish and Fishery Product Processing Methods, Hazards and Controls
http://seafood.ucdavis.edu/haccp/compendium/compend.htm

SELECTED ADDITIONAL REFERENCES

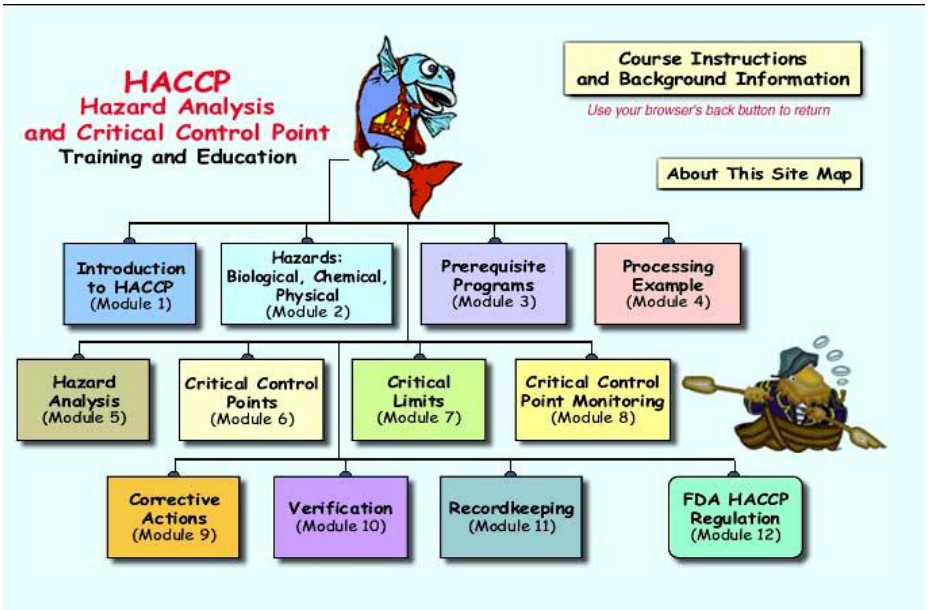
FDA/DHHS. 1994. "**Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products**," Government Printing Office, Washington, DC 20402 (202/512-2357), Jan. 28, 1994. Federal Register, pages 4142-4214.
Federal Register 60 FR 65095 December 18, 1995. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule. 21 CFR 123 and 1240. Part I, Preamble, pp. 65095-65152
Federal Register 60 FR 65095 December 18, 1995. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule. 21 CFR 123 and 1240. Part II, Preamble, pp. 65152-65197
Federal Register 60 FR 65095 December 18, 1995. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule. 21 CFR 123 and 1240. Part III, Regulation, pp. 65197-65202
http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/SeafoodHACCP/ucm111304.htm

Lee, J.S. and K.S. Hilderbrand 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. http://nsgd.gso.uri.edu/oresu/oresuh92001.pdf (Requires Adobe Acrobat Reader)

Microbiology and Food Safety Committee, National Food Processors Association (NFPA). 1989. "**Guidelines for the Development of Refrigerated Foods**," NFPA Bulletin 42-L, 1989. "Out of Print" and scheduled to be updated. A limited number is available upon special request to the Food Products Association (Phone: 1-800-355-0983).

NACMCF. 1992 Hazard Analysis and Critical Control Point Principles and Application Guidelines. Adopted August 14, 1997. National Advisory Committee on Microbiological Criteria for Foods. http://vm.cfsan.fda.gov/~comm/nacmcfp.html
Subcommittee on Microbiological Criteria. Committee on Food Protection, Food and Nutrition Board, National Research Council, NAS. 1985. "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients," National Academy Press. http://books.nap.edu/books/0309034973/html/index.html

Seafood HACCP Alliance Internet Training Course



Seafood HACCP Training on the Internet

The National Seafood HACCP Alliance has developed a Seafood HACCP training course that is available on the Internet. This Internet-based distance education program is designed to be equivalent to the first two days of the "live" three-day Alliance training courses conducted across the U.S. over the past 10 years. The Internet course is managed by New York Sea Grant and Cornell University. The Seafood HACCP Internet training course was developed by the Alliance in collaboration with the FDA, the Association of Food and Drug Officials, New York Sea Grant, and Cornell University.

For additional information on the Alliance Internet course contact: Ken Gall by Email at klg9@cornell.edu or call Ken Gall or Karen Palmeri at 631-632-8730.

How the Course Works

Seafood HACCP training is now available on demand. You can register for the Internet course at any time and complete the course materials at your own pace wherever you have a computer with an Internet connection. There are 12 training Modules in the course that cover all of the information on HACCP principles, their application to seafood products, and the FDA regulation presented in the first two days of the regular Alliance training course. After registering, each student will be tracked by their unique Username and Password. Students who complete all 12 Modules will receive an Email letter from Cornell acknowledging that they have completed "Segment One" of the Alliance training course.

Those who want to receive a "Certificate of Course Completion" from the Association of Food and Drug Officials (AFDO) to meet the training requirement of the FDA Seafood HACCP regulation will then need to attend a 1-day live "Segment Two" training session conducted by a trained instructor. Your Email letter from Cornell showing that you've completed the Internet course will be your "ticket" to an AFDO registered "Segment Two" training session.

Firms that already have "HACCP trained" individual(s) can use the Internet course to train additional employees. Your employees can complete the Internet course at work or at home, and you won't have to send them to a three-day course if AFDO certification is not needed. Experience has shown that HACCP implementation can be more effective when a number of key people in the operation have a good understanding of the system and its requirements.

How to Use The Seafood HACCP Internet Course

Step 1 – Go to **http://seafoodhaccp.cornell.edu** at any time to find out how the Internet course works, what you will need to take the Internet course, and to order the training manuals online or by phone.

Step 2 – Go to the registration section at **http://seafoodhaccp.cornell.edu** and fill in and submit the Registration form and your credit card payment for the registration fee of $50.00. You can also select a "Register by Mail" option and print out a registration form and send it with your payment by regular mail.

Step 3 - When your registration and payment have been processed, you will receive an Email message telling you how to obtain a Cornell Guest ID and create and activate a Username & Password, which you must have to get to the course site.

Step 4 – When your Cornell Guest ID has been activated, an enrollment Email message will give you the location of the active course site with the 12 Course Modules. You will need to submit answers to a series of questions at the end of each Module while you are logged in with your Username and Password. Your progress will be automatically tracked as you submit your answers for each Module.

Step 5 – When all Modules are completed, an Email letter from Cornell and the Alliance will be sent to the person who registered for the course to prove that they have completed the Seafood HACCP Alliance Segment One Internet training course.

Step 6 – Register for a Second Segment one day "live" training session if you need an AFDO Certificate of Course Completion to meet the training requirement in the FDA Seafood HACCP regulation or if you have questions or need additional experience developing a HACCP Plan. A current list of registered courses can be found at **http://seafood.ucdavis.edu/haccp/training/masterca.htm**

Jan. 2006

HACCP & SCP Training Protocol

September 9, 2009

PROTOCOL CHANGES (anticipated before end 2009)

(New Protocol Committee – L. Weddig (Chr), with L. Stambaugh, P. Tom. G. Wolfe and S. Otwell)

- Add wording and new outline for **course agenda** to feature the order of chapter titles in the new training manual and the optimum **course duration** (2.5 days) with allowances for flexible agendas (less than 2.5 days, but no less than 2.0 days/16 contact hours), noting that any application for less than 2.5 days must include justifications based on nature of the audience. Explain 'nature' of the audience.

  Must also alter the Alliance **course application form** to include a section to explain the intended course agenda and any necessary justification for courses less than 2.5 days.

- Omit audit requirements for **international courses so as to be equivalent** with domestic courses. May consider omitting terms 'international and domestic' courses since the only difference will be the $100 application fees.

- Add wording to emphasis trainers should **schedule and post Segment II courses** on both websites, AFDO & UC-Davis.

- Add wording to address **trainer 'applications' and 'qualifications'** that include two recommendations that can support their ability and intentions to provide such training in an informed and uniform manner consistent with AFDO/Alliance protocol. The recommendations are to accompany the applications to attend a Train the Trainer course. May need to modify the course application forms.

- Add wording to address **trainer 'qualifications' and 'requirements'** that include necessary revisions and updates to maintain 'approved' status that assures current trainer knowledge and uniform training consistent with new regulatory requirements and new Alliance training materials. The protocol can indicate all intentions to assure a practical approval process. Details for the process do not need to be itemized in the protocol, but trainers should be directed to sources of information to maintain approved status. Also, need to add wording that allows future revised training requirements as needed.

- Add new process to review TT applicants

ASSOCIATION OF FOOD & DRUG OFFICIALS
and
SEAFOOD HACCP ALLIANCE
(AFDO/ALLIANCE)

HACCP & SCP TRAINING PROTOCOL

Edition 05-01-06

This protocol is provided to ensure a uniform and cost-effective AFDO/Alliance hazard analysis and critical control point (HACCP) training program for the processing and importing of fish and fishery products for commerce in the United States. The current protocol is addressed at least annually by the Seafood HACCP Alliance Steering Committee working in collaboration with the AFDO Board of Directors and selected AFDO Committees. Inquiries can be directed to the AFDO headquarters in York, Pennsylvania.

AFDO - The Association of Food and Drug Officials is a professional organization of food and drug officials involving all pertinent state and federal regulatory agencies in the United States addressing food safety, and related commercial interests. Their membership is open to similar international regulatory programs and to academic, commercial and other private interests.

Seafood HACCP Alliance - The ′Alliance′ is a collaborative project initially funded by the National Sea Grant College Program to develop a standard training and education program to assist the commercial and regulatory implementation of U.S. Food & Drug Administration's (FDA′s) mandatory seafood HACCP inspection programs. AFDO and FDA have provided additional funding and staff support to continue the Alliance's educational activities. The Seafood HACCP Alliance Steering Committee involves representation from three federal agencies, the Food & Drug Administration, US Department of Agriculture-CSREES, and US Department of Commerce-Seafood Inspection Program, the various state agency organizations through AFDO regional affiliates, and the Interstate Shellfish Sanitation Conference, and the industry trade associations, National Fisheries Institute and Food Products Association.

Association of Food and Drug Officials
2550 Kingston Rd., Suite 311, York, PA 17402

AFDO/ALLIANCE HACCP TRAINING PROTOCOL

1.0 PURPOSE

The primary purpose of the AFDO/Alliance HACCP Training Protocol is to assist the implementation of HACCP programs in commercial and regulatory settings. The assistance is provided through a uniform, cost-effective education and training program. This program includes standardized courses, training materials and trained instructors. Courses have been developed for training in basic HACCP programs and the related Sanitation Control Procedures (SCP). The training is consistent with the regulatory mandates for processing and importing fish and fishery products for commerce in the United States. The primary audience is the seafood processing and importing industry, and regulatory officials based in the United States. Mindful of equivalent regulatory expectations for seafood processors in other countries, this program may be provided for international audiences. Persons that complete the AFDO/Alliance courses will receive Certificates of Course Completion from the Association of Food and Drug Officials (AFDO). The certificates for the basic HACCP programs denote completion of a standard training program in the application of HACCP principles to fish and fishery processing as referenced by the U.S. Food and Drug Administration (FDA; 21 CFR Part 123; Dec. 18, 1997) and the respective State HACCP regulations.

2.0 PROCESS

2.1 The Seafood HACCP Alliance in conjunction with AFDO developed and maintains the uniform HACCP and SCP training manuals, course outline and associated materials. This collaborative effort is denoted as the AFDO/Alliance Seafood HACCP Training Program.

2.2 The Seafood HACCP Alliance Steering Committee will arrange Train-the-Trainer courses to prepare "qualified" instructors. An assigned AFDO/Seafood Committee will review the course registration forms for conducting Basic Training Courses for both domestic and international courses.

2.3 AFDO will maintain records of registered courses, qualified instructors, course evaluations and course graduates receiving AFDO/Alliance Certificates of HACCP and SCP Course Completion.

2.4 All domestic HACCP and SCP courses registered with AFDO are encouraged to collaborate with the AFDO regional affiliates. International courses registered with AFDO must be conducted through the AFDO headquarter office.

2.5 An optional internet HACCP course is maintained through the Cornell University/New York Sea Grant Program (see Section 3.3). This course is recognized by the Alliance through content and completion of a 'Segment Two' course that provides equivalent AFDO Certificates of Course Completion.

2.6 All one-day "Segment Two" training courses must be registered through the AFDO office and are encouraged to collaborate with AFDO regional affiliates.

2.6 Alliance course information and materials can be accessed through a website maintained by the University of California-Davis/ California Sea Grant Extension Program (http://www-seafood.ucdavis.edu/haccp/ha.htm)

3.0 COURSES

3.1 **Train-the-Trainers Courses:** Train-the-Trainer courses are designed to qualify instructors to conduct the uniform AFDO/Alliance basic training courses. The trainer courses are taught by experienced AFDO/Alliance appointed instructors familiar with the Core Training Manuals and associated materials for HACCP and SCP. Participants completing the trainer course are 'qualified' instructors for the basic training courses consistent with the AFDO/Alliance HACCP Training Protocol.

3.1.1 HACCP Train-the-Trainer course – the 2-day format, will be taught by at least two "qualified" HACCP instructors.

3.1.2 SCP Train-the-Trainer course – 1 day format, either continuous or consecutive half days taught by at least two qualified" SCP instructors.

3.2 **Basic Training Course:** Basic courses are designed for persons working in commercial and regulatory settings or related professions that can influence and/or involve seafood and/or aquaculture product safety. This course must use the AFDO/Alliance training materials and should follow the uniform course outline. In keeping with the FDA HACCP mandate for fish and fishery products (21 CFR Part 123), this course focuses on product processing, which can relate to production, importing into the United States and additional commerce. Instruction for this course must include at least one AFDO/Alliance "qualified" instructor present for the duration of the course. HACCP courses require HACCP 'qualified' instructors, and SCP courses require SCP 'qualified' instructors. One ′qualified′ instructor will serve as the course ′supervisory′ instructor. In addition to requirements for course supervision, international courses will be subject to AFDO/Alliance audit requirements (see sec. 10.0).

3.3 **Internet HACCP Course:** An optional Alliance Internet based 'Segment One' training course is designed to teach students the information presented in the basic HACCP curriculum. Students must register for the course at www.seafoodhaccp.cornell.edu and complete all 12 course modules within 6 months of the processing of their registration. Students who complete the Internet training course can present their Email notification of course completion from the Cornell University/New York Sea Grant Program to be eligible to attend an optional one-day 'Segment Two' training session conducted by a "qualified" HACCP instructor. Students completing the Segment Two course will receive an AFDO Certificate of Course Completion for the basic HACCP training.

4.0 COURSE MATERIALS

4.1 **Core Training Manuals*:*** The training manuals include: 1) HACCP Training Curriculum and 2) Sanitation Control Procedures (SCP) developed by the Alliance. Basic chapters address implementation of HACCP and SCP programs consistent with recommendations by the National Advisory Committee on Microbiological Criteria for Foods and FDA′s mandated HACCP Program for Fish and Fishery Products (21 CFR Part 123, Dec. 18, 1995). Course addendums include model HACCP programs and Sanitation Standard Operating Procedures (SSOP's) for instructional purposes and reference. An additional Alliance reference, the Compendium of Fish and Fishery Product Processes, Hazards, and Controls, is accessible in electronic format:

http://seafood.ucdavis.edu/haccp/compendium/compend.htm

4.2 **FDA's Fish and Fishery Products Hazards and Control Guidance**: A guide prepared by the FDA to assist in hazard analysis and HACCP program development; "FDA Hazards Guide"

4.3 **Source**: The HACCP and SCP Training Manuals, and FDA′s ′Hazards Guide′ can be obtained as individual copies on a cost recovery basis from:

IFAS-Extension Bookstore
University of Florida
P.O. Box 110011
Gainesville, FL 32611-0011
800-226-1764 or 352-392-1764 or
Credit card orders may be placed 24 hours a day online at http://ifasbooks.ufl.edu

A Spanish version of the HACCP and the SCP training manual is also available.

Translations of the training manuals must be previewed and recognized by the Seafood HACCP Alliance and AFDO before they can be used in training to fulfill the requirement of the AFDO/Alliance HACCP Training Protocol.

5.0 BASIC COURSE REGISTRATION

5.1 Basic course 'registration' means the course is recognized as being registered by the AFDO/Seafood HACCP Alliance (see sec. 6.0) and the persons completing the courses are eligible to receive the AFDO/Alliance Certificates of Course Completion. FDA and related regulatory authorities can reference these certificates as evidence for completion of a standard HACCP or SCP training program for fish and fishery products as specified in section 123.10 *Training* in the FDA Code of Federal Regulations Title 21, Part 123- Fish and Fishery Products.

5.2 Course Registration Process:

5.2.1 Applications for basic course registration (Appendix I) must be completed and submitted to:

AFDO
2550 Kingston Road, Suite 311
York, PA 17402
Ph 717-757-2888 for information and application forms
Fax 717-755-8089
Website provides details & forms:
http://www.afdo.org/Training/HACCP/Seafood/Instructors.cfm

5.2.2 The AFDO Office will forward the applications for domestic and international course registration to the assigned AFDO/Seafood Committee for review and comment. Response can be:

-Registration complete
-Registration pending modifications (itemized)
-Registration denied

5.3 Basic Course Registration Requirements

Failing to meet one of the following requirements is grounds for denial of course registration.

5.3.1 Applicants must use the Alliance developed Core Training Manuals and associated materials in a standard course outline, plus FDA's Hazards Guide for Fish and Fishery Products. Any translations of the current approved English version must be previewed and recognized by the Seafood HACCP Alliance Steering Committee and the AFDO/Seafood Committee.

5.3.2 The course 'supervisory' instructor must be present for the duration of the course (see Section 9.3).

5.3.3 In addition to the supervisory instructor, international courses must include a pre-approved auditor present for the duration of the course (See Section 10.0).

5.3.4 Applicants to conduct domestic HACCP courses are encouraged to inform and cooperate with the regional AFDO affiliate. The course should identify the name of the affiliate and the affiliate contact person in liaison with the affiliate's executive committee. All SCP courses are also encouraged to collaborate with the regional AFDO affiliate. Current contacts for regional AFDO affiliates are available via the AFDO website (http://www.afdo.org/afdo/affiliates.cfm).

5.3.5 International courses shall be conducted in cooperation with the national AFDO organization through liaison with the AFDO headquarters and Executive Committee.

5.3.6 The projected cost of the course and registration fees must be consistent with the Alliance and AFDO's intentions to minimize costs for training (see Section 8.0). Fees for international courses must be paid in U.S. currency for the basic AFDO fees and the Training Materials (Core Training Manual and FDA Guide).

5.3.7 Credits for previous HACCP or SCP training will not be considered relative to issuing the AFDO/Alliance Certificates of HACCP or SCP Course Completion.

5.3.8 Segment Two one-day training sessions for students who have completed the Alliance Segment One Internet training course must be conducted by a "qualified" instructor. The course must be registered and approved by AFDO headquarters for students to be eligible to receive a Certificate of Course completion for the basic HACCP course. Students must provide proof of completion of the Internet Segment One course to be eligible to attend a Segment Two session. Projected costs and registration fees for Segment Two sessions must be consistent with the Alliance and AFDO's intentions to minimize costs for training (see Section 8.0).

Basic Course Recommendations:

The preferred instructor-to-student ratio for the basic HACCP course is 3 instructors per 25-30 students. The preferred instructor to student ratio for the 1-day SCP course is 2 instructors per 25-30 students. These ratios allow for more student and instructor interaction, which is an important attribute of the AFDO/Alliance Seafood HACCP and SCP Training Programs.

6.0 AFDO / SEAFOOD COMMITTEE

Course applications will require a review coordinated through an assigned AFDO/Seafood Committee.

6.1 The AFDO/Seafood Committee Chair will be appointed by the President of AFDO. The appointments will consider affiliation with AFDO, regulatory, commercial and academic representation and pertinent HACCP knowledge and experience, particularly as related to the AFDO/Alliance Seafood HACCP Training Program and materials. The Seafood Committee Chair will appoint representatives from the regional affiliates to review the course applications.

6.2 The AFDO/Seafood Committee Chair will appoint members to review international courses.

7.0 REVOCATION OF COURSE REGISTRATION

7.1 The following items are just cause for the AFDO to revoke any prior registered course. Revocation disqualifies a course and AFDO/Alliance Certificates of HACCP Course Completion become null and void.

7.1.1 Failure to conduct training according to the AFDO/Seafood HACCP Alliance course registration requirements.

7.1.2 Failure to pay the appropriate fees for any course.

7.1.3 Submission of an intentionally false Course Completion Report (i.e., misidentified instructors, students, dates, locations or course outline).

7.1.4 Responses indicating inappropriate instruction and/or failure to conduct training according to the AFDO/Alliance Basic Training course registration requirements. Inappropriate instruction can include concern for students listening and reading comprehension of the language used during instruction and in training materials.

7.1.5 If courses are taught without prior AFDO/Alliance approval, certificates will not be issued.

8.0 FEES

The AFDO/Alliance Seafood HACCP Training Program is intended to minimize the cost for training for the domestic audience. The total basic training cost per student registration fees should include the following items, exclusive of incidental costs, e.g., refreshments, equipment and facility rentals, etc.

Incidental costs should be itemized on the course registration form. (Note: Costs are subject to change depending on changes in training material production and distribution costs).

8.1 (HACCP) For domestic HACCP courses, payments ($40/set/student) for the Alliance's HACCP Core Training Manual (SGR-120 or SGR-125-Spanish) and FDA's Fish and Fishery Products Hazards and Control Guide (SGR-121) can be pre-arranged through IFAS-Extension

Bookstore. Purchases must be pre-paid before delivery. In situations that can not predict or afford pre-payments, the IFAS-Extension Bookstore has made special arrangements for invoicing through the AFDO regional affiliates. Instructors would have to coordinate such invoicing with the AFDO regional affiliates. After payment or invoicing, the manuals can be shipped to the requesting instructor. For international courses, payments for HACCP training manuals must be paid in advance directly through the distribution center, IFAS-Extension Bookstore, and must include any extra handling and distribution costs.

For domestic and international HACCP courses and for students completing the Internet HACCP course plus the Segment Two one-day training course, a fee ($30/student paid to AFDO) is necessary to obtain the Certificate of Course Completion which is registered by AFDO. The fee is necessary to reimburse AFDO for their services for registering HACCP courses, coordinating 'qualified' instructors and train-the-trainer courses, maintaining training protocol, and processing and recording the Certificates of HACCP Course Completion.

8.2 (SCP) For domestic or international SCP courses, payments for the Alliance's SCP Training Manuals (SGR-119 or SGR-122-Spanish; $25/ manual) should be pre-arranged directly with the distributor, IFAS-Extension Bookstore, and must include any necessary handling and distribution costs.

8.3 (SCP) For domestic or international SCP courses, a fee ($20/student paid to AFDO) for registering SCP courses, coordinating 'qualified' instructors and the train-the-trainer courses, maintaining training protocol, and processing and recording the Certificates of SCP Course Completion must accompany the student list (email Excel spreadsheet) submitted to AFDO following successful completion of the course.

8.4 (HACCP & SCP) For domestic HACCP and SCP courses, a fee for the AFDO regional affiliate ($15/student paid to the AFDO regional affiliate) is required for regional course facilitation. If the regional affiliate is not involved in any aspect of the meeting arrangements or actual training, this fee can be considered optional. Likewise, additional affiliate fees may be required depending on the role of the affiliate. Experience has shown their role can differ per region and training events. There is no structured regional affiliate fee requirement for Segment Two one-day training sessions for the Internet delivered basic HACCP training course.

An initial prepaid course application fee ($100) must accompany each international course application. This fee is necessary to support the AFDO course registration process and international expenses. One fee is necessary for each course. This fee is non-refundable.

The registration fee for the Segment One Internet based HACCP training course is $50, which is paid by students directly to the host organization for this site, the Cornell University/New York Sea Grant Program.

Summary of Course Fees per Student ($US)

	Training Manuals	AFDO Registration & Certificate	*AFDO Regional Affiliate	Totals per Student
HACCP_ Course	HACCP & FDA Guide $40/set	$30	$15 (optional)	$75 - $85
SCP Course	SCP manual $25 each	$20		$45
Internet Course Segment One	Internet Course** $50			$50
Internet Course Segment Two		$30***		$30

* The fee for the regional AFDO affiliate will depend on the arrangements and involvement of the respective AFDO affiliates.

** Cost for the Internet course can also involve the student purchase of the HACCP training manual and accompanying FDA Guide ($40/set).

***The 'Segment Two' course is optional and requires a fee payable to AFDO to obtain the formal Certificate for Courses Completion.

8.5 **Recommended Methods of Payment:**

Recognizing a variety of possible financial arrangements, the AFDO /Alliance program recommends the following methods of payment. Alternative payment methods for domestic courses must be prearranged with and/or coordinated with the AFDO regional affiliate. Payments for international courses must be paid in U.S. currency in advance as outlined.

8.5.1 Domestic HACCP courses: The 'supervisory' instructor directs the necessary payments for training manuals ($40/set) to the IFAS-Extension Bookstore and student registration fees ($30/student) to AFDO. The 'supervisory' instructor is responsible for all additional training fees. If the regional AFDO affiliate is involved, the 'supervisory' instructor can direct registration payments to the account of the AFDO regional affiliate (i.e., AFDOSS, MCA, WAFDO, NCAFDO, CASA or NEFDOA). The 'supervisory' instructor is encouraged to use checks instead of cash. Payments can be by personal check, cashier's check or money order. All collected student registrations are to be forwarded to the respective AFDO regional affiliate treasurer by the supervisory instructor (see Official Listing; http://www.afdo.org/Training/HACCP/Seafood.cfm)

The AFDO regional affiliate treasurers draft appropriate payments per student registration to IFAS-Extension Bookstore ($40/student), AFDO ($30/student), and the local facilitators. The AFDO regional affiliate retains the regional training fee ($15/student).

8.5.2 Domestic SCP Courses: The 'supervisory' instructor directs the necessary payment for training manuals ($25/manual) to Florida Sea Grant/IFAS-Extension Bookstore and student registration fees ($20/student) to AFDO. The Supervisor is responsible for all additional training fees.

8.5.3 International Courses: The 'supervisory' instructor submits a completed course registration form to AFDO headquarters with the necessary application fee ($100/course).

The international course 'supervisory' instructor prepays for the necessary training materials from the appropriate distribution center.

Following completion of the course, the international course 'supervisory' instructor sends all student registration fees ($30/student for HACCP or $20/student for SCP) in U.S. currency to AFDO.

8.5.4 Internet Training Course: Segment One fees are paid directly by credit card, personal check, cashiers check or money order to the Cornell Food Industry Management Distance Education Program. Course manuals can be ordered directly via the Internet or by phone from the IFAS-Extension Bookstore.

Fees for the "Segment Two" one-day training sessions will be collected by the course supervisory instructor who is responsible for collecting and forwarding the fee of $30/student to AFDO before Certificates of Course Completion will be issued.

AFDO WILL ONLY ISSUE
"CERTIFICATES OF HACCP OR SCP COURSE COMPLETION" AFTER ALL FEES ARE PAID.

9.0 QUALIFIED AND SUPERVISORY INSTRUCTORS

9.1 All AFDO/Alliance Seafood HACCP Training Programs must include at least one 'qualified' instructor to be present for the duration of the standard 3-day basic HACCP or 1-day SCP training program. More than one 'qualified' instructor is preferred.

9.2 '**Qualified' instructors** are persons who have completed a Train-the-Trainer course offered by the Seafood HACCP Alliance in conjunction with AFDO. HACCP 'qualified' instructors must complete the Alliance's HACCP Train-the-Trainer course. SCP 'qualified' instructors must complete the Alliance's SCP Train-the-Trainers course. These persons are selected and

recommended by AFDO, the Alliance Steering Committee or the AFDO regional affiliates. Selection criteria include:

9.2.1 Persons having a background of training and experience in food science, food microbiology and/or food chemistry, sanitation in food processing or related fields.

9.2.2 Persons with some prior experience and understanding of HACCP systems and/or sanitation in food processing for food safety.

9.2.3 Domestic courses: Persons willing to and are expected, through job assignment, to assist AFDO regional affiliates and States conducting basic seafood and aquaculture HACCP and SCP training in a cost-effective manner.

9.2.4 International courses: Persons familiar with and involved in the respective country seafood and aquaculture processing, commerce and/or food safety regulations, and are expected and capable for training the intended commercial and regulatory audience.

9.3 A '**supervisory' instructor** is an Alliance 'qualified' instructor responsible for organizing and directing the basic training course, and is also responsible for collecting registration fees, compiling the course evaluations and preparing a Course Completion Report with students identified to receive AFDO/Alliance Certificates of Course Completion.

10.0 COURSE AUDITS

AFDO reserves the right to arrange audits to monitor registered courses eligible for AFDO/Alliance Certificates of Course Completion.

10.1 Domestic course audits may be arranged through the AFDO Seafood Committee Chair.

10.2 International course audits are required. The auditor must be a representative of the recognized regulatory program responsible for inspecting and maintaining standards for seafood safety in commerce and processing in the respective country where the course will be taught. The AFDO Seafood Committee will only register courses with approved auditors through reference to the most current program listings in the U.S. FDA International program listings and/or additional auditors as deemed appropriate. In exceptional instances where a government official is unavailable to perform the auditor function, an alternative will be considered on a case-by-case basis. Please contact the AFDO Seafood Committee Chair for guidance.

11.0 ALLIANCE/AFDO RECORDS

11.1 AFDO's headquarters will maintain records of a) 'qualified' instructors, b) registered courses, c) course evaluations, d) course audits, and e) persons receiving Certificates of Course Completion.

12.0 CERTIFICATE OF COURSE COMPLETION

12.1 The AFDO/Alliance Certificates of Course Completion will denote completion of a uniform, standard HACCP or SCP training course for fish and fishery products safety. (Addendum: Basic Course Outlines).

12.2 Students **must** attend all days of scheduled training for the HACCP or SCP courses, or complete the Segment One Internet training course AND a Segment Two training session conducted by a qualified instructor, in order to receive the AFDO/Alliance Certificate of HACCP or SCP Course Completion. Situations that terminate or limit student completion of the necessary day(s) of training will be noted on the student's registration form in order to assure credits for the days or time completed and to assure registration fee credits for future courses. Further training will be necessary to complete the course and be eligible for the AFDO/Alliance Certificate. Additional registration fees should only include costs for local facilities and arrangements.

12.3 Dates and location of training will be listed on each certificate.

12.4 Certificate signatures in recognition of the training will include the current AFDO President.

12.5 Certificates <u>may</u> list organizations coordinating and providing the training if pre-approved by AFDO.

12.6 Certificate distribution should follow successful completion of the standard course, submission of the Course Completion report and verification of paid fees.

13.0 <u>RESPONSIBILITIES</u>

Responsibilities are listed in most probable sequence of events for a basic training course.

1. For domestic courses, the course applicant(s) are encouraged to initially contact the AFDO regional affiliate to establish liaison and announce intentions to provide a basic course in accordance with AFDO/Alliance Training Protocol. One of the course applicants must be a supervisory instructor. This initial contact should address any necessary financial arrangements and establish liaison with AFDO and/or the AFDO regional affiliate and representative(s). **Working with and through a regional AFDO affiliate is encouraged but not mandated.**

   An application for course registration is submitted to AFDO. The application form must be obtained and completed by the applicants including a 'supervisory' instructor. Expect 20 to 30 days for final response.

   International course applications must be accompanied by the application fee ($100/course) payable in U.S. currency.

2. The AFDO headquarter office forwards the applications through the AFDO/Seafood Committee Chair for their review. Responses are compiled by the Committee Chair and forwarded back to the AFDO office for reply to the applicants. Responses can Be: registration complete, registration pending modifications (itemized), or registration denied.

3. If the review response is “registration complete”, the AFDO/Seafood Committee Chair will request that the AFDO office send an AFDO registration packet and Course Completion Report form for student registration. The applicants can proceed with the course anticipating official AFDO/Alliance Certificates of HACCP Course Completion for all students completing the course. The AFDO office will record the registered course information.

   The applicant must order the necessary amount of training materials per anticipated students from the appropriate distribution center(s).

4. The training proceeds. The ‘supervisory’ instructor must be present for the duration of the training session. Also, approved auditors must be present for the duration of international courses.

   When the course is completed, the original applicant/supervisory instructor must forward the Course Completion Report listing the course graduates to the AFDO office. This list will be prepared per previous AFDO instructions provided to all applicants with the registration packet.

5. After the training is completed, the totaled student registration fees are forwarded to AFDO with the course completion report.

6. The AFDO headquarter office will record the student graduates and prepare the students’ Certificates of Course Completion. Completed certificates will be mailed to the domestic students according to their registered listing. **International student certificates will be mailed to the course supervisory instructor for their distribution to the students.**

7. Students must demonstrate that they have completed the Alliance Internet Training course to be eligible to participate in a Segment Two training session and receive an AFDO/Alliance Certificate of Course Completion. Supervisory instructors for Segment Two one-day training sessions must follow all requirements and responsibilities outlined above for the basic HACCP training course.

APPENDIX I.

BASIC HACCP TRAINING COURSE

DAY ONE

15-20 min. **ORIENTATION AND COURSE OBJECTIVES**
- -Introduce instructors and training materials
- -Describe the purpose of the course
- -Explain the relationship of the Alliance and AFDO
- -Introduction to HACCP for food safety

75 min. **FOOD SAFETY HAZARDS**
- -Biological (brief review of types, concerns and controls)
- -Chemical (same)
- -Physical (same)
- -Introduce Hazards Control Guide (FDA, 1996)

30 min. **PREREQUISITE PROGRAMS AND PRELIMINARY STEPS**
- -Review programs that need to be in place before implementation of a HACCP program
- -Distinguish sanitary standard operating procedures (SSOP's), good manufacturing practices (GMP's) and HACCP
- -Introduce preliminary planning steps for development of a HACCP program. (Flow diagram for processing I.Q.F. Cooked Shrimp, the training model processing operation).

BREAK

90 min. **CONDUCTING A HAZARD ANALYSIS**
- -Use the shrimp processing model to illustrate why and how to conduct an initial hazard analysis.
- -Incorporate reference to FDA's 'Hazard Guide'
- -Introduce the Hazard Analysis Form

LUNCH

60 min. **DETERMINING CRITICAL CONTROL POINTS**
- -Define critical control points (CCP's)
- -Continue with shrimp example to identify CCP's
- -Discuss the 'Decision Tree' approach
- -Use additional examples

60 min. **ESTABLISHING CRITICAL LIMITS**
- -Define and list typical critical limits (CL's)
- -Continue to develop the shrimp example
- -Introduce the HACCP Plan Form
- -Reference use of FDA's Hazards Guide
- -Discuss use of operating limits

BREAK

40 min. **MONITORING CRITICAL CONTROL POINTS**
- -Develop monitoring procedures for the shrimp example
- -Define and explain the purpose for monitoring
- -Provide additional examples

40 min. **CORRECTIVE ACTIONS**
- -Define and explain need for predetermined corrective actions
- -Expand shrimp example
- -Provide additional example

ADJOURN day one

DAY TWO

60 min. **RECORDKEEPING PROCEDURES**
-Describe recordkeeping procedures through continued development of the shrimp example
-What constitutes a viable, valid record?
-Distinguish HACCP and SSOP (sanitation) records and requirements
-Discuss record storage and retrieval (text and electronic)

60 min. **VERIFICATION**
-Define verification
-Complete the HACCP Plan Form for the shrimp example
-Provide various examples and contrast with government verification/inspection
-Discuss frequency for verifications

BREAK

90 min. **OVERVIEW OF FDA SEAFOOD HACCP REGULATION**
-Discuss key points in the seafood mandate
-Describe interrelations of HACCP mandate with other directives

LUNCH

90 min. **OVERVIEW OF FDA SEAFOOD HACCP REGULATIONS**
-continued

BREAK

45 min. **SEAFOOD SPECIFIC HAZARDS**
-Identify key hazards of concern and review controls
-Reference FDA's Hazards Guide

30 min. **SOURCES FOR IDENTIFYING HAZARDS AND DETERMINING CONTROL MEASURES FOR SEAFOODS**

60 min. **REVIEW AND PREPARATION FOR DEVELOPING HACCP PLANS: PRACTICAL WORK SESSION**

ADJOURN day two

DAY THREE

Morning **GROUP WORK SESSIONS ON DEVELOPING HACCP PLANS**

LUNCH

Afternoon **WORK SESSIONS (continued)**

60 min. **WRAP-UP** and ADJOURN day three

APPENDIX II.

INTERNET HACCP COURSE

An optional Alliance Internet based training course is designed to teach students the information presented in the basic HACCP curriculum.

SEGMENT ONE –Students must register for the Internet course at http://seafoodhaccp.cornell.edu The Internet course consists of 12 modules, each of which corresponds to the chapters in the Alliance training manual. Students will work through the 12 modules in the same order as the chapters in the HACCP manual. Each student's progress through the Internet course will be tracked by the Username and Password that they will create after registering for the course. When the Internet course is completed, an Email letter of Course Completion from Cornell University and the Seafood HACCP Alliance will be sent to the student to provide proof that they have completed Segment One of the Seafood HACCP Alliance Training Program. This notification will serve as the student's "ticket" to attend a Segment Two one-day Alliance HACCP Training Program. All 12 Internet course modules must be completed within 6 months of the processing of the initial Internet course registration.

SEGMENT TWO – One additional day optional training for students that desire additional training in order to receive the AFDO Certificate of Course Completion. The Segment Two course must be provided in person by a qualified AFDO/Alliance instructor. The following Segment Two course format and agenda is suggested.

15-30 min. **ORIENTATION AND COURSE OBJECTIVES**

-Introduce instructors and students
-Verify that each student has completed the Internet-based Segment One course
-Explain training protocol, relationship of the Alliance and AFDO and training requirement of FDA seafood HACCP regulation

60-90 min. **REVIEW AND Q & A**

-Seafood Safety Hazards
-Prerequisite Programs and Preliminary Steps
-7 HACCP principles
-Relationship of HACCP to FDA regulation
-FDA Guidance material (Hazards Guide)
-Work through part of ABC Shrimp or other model if necessary to review the process of developing a HACCP plan

DIVIDE STUDENTS IN TO APPROPRIATE WORK TEAMS AND REVIEW AND SELECT MODELS

GROUP WORK SESSIONS TO DEVELOP HACCP PLANS USING MODELS IN ALLIANCE training manual

PRESENTATION AND DISCUSSION OF GROUP WORK SESSION RESULTS

WRAP-UP

-Summary/concluding comments
-Q & A period for any remaining student questions
-Ensure that student rosters are correct for AFDO Certificates of Course Completion
-Evaluation and Course Completion Report

APPENDIX III. Sanitation Control Procedures Course

I-3. Course Chapters – 3 Parts:

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

I-4. Basic SCP Course

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

AFDO/ALLIANCE SEAFOOD HACCP TRAINING PROGRAM

DOMESTIC COURSE REGISTRATION FORM

Submit this form with the requested documentation to the Association of Food and Drug Officials, 2550 Kingston Rd., Suite 311, York, PA 17402 (717-757-2888; fax 717-755-8089).

SUBMIT ONE COMPLETE APPLICATION FOR EACH COURSE DATE AND LOCATION

Legible and complete applications assure a prompt response!

1. Applicant _____
   Last name First name MI
   Title _____
   Address _____
   Phone _____ / Fax _____
   E-mail _____
2. Course (Check one): HACCP 3-day[ ] or SCP 1-day [ ] or Segment Two 1-day [ ]
   Course Date/Location _____ / _____
   Expected Number of Students _____
3. Instructors and qualifying credentials. **Attach brief vitae with addresses and telecommunications.** Include certificate numbers for all the AFDO/Alliance 'qualified' instructor(s).
   a. *Supervisory Instructor _____
   b. _____
   c. _____
   * Supervisory Instructor must be AFDO _qualified_ according to the AFDO/Alliance Seafood HACCP and SCP Training Protocol and be present for the duration of the course.
4. AFDO Affiliate Liaison
   Organization Executive Member _____
   Address _____
   _____
   Phone/Fax _____/_____
   Any role in program _____
5. Course outline (submit for review of topics, schedule and instructor assignments). Reference the Basic Course Outline.
6. List training materials to be used in addition to the AFDO/Alliance Core Training Manual and FDA's Hazard Guide for Fish and Fishing Products.
7. Course registration fee: Total cost/student $ _____
   Registration fee must include:
   1) $30 per HACCP student or $20 per SCP student to AFDO for recording and preparing the AFDO Certificates of Course Completion
   2) $40 for the HACCP or $25 for the SCP training manuals.
   3) $15 per student for Regional Affiliate if utilized.

Additional Costs/Student Specific Justifications

(Use additional page if necessary)

Signature of the applicant and/or Supervisory Instructor denoting agreement to conduct the described training in accordance with the AFDO/Alliance Seafood HACCP and SCP Training Protocol and to be responsible for all itemized fees.

Name:_____ Date _____

AFDO/ALLIANCE SEAFOOD HACCP TRAINING PROGRAM

INTERNATIONAL COURSE REGISTRATION FORM

Submit this form with the requested documentation to the:
Association of Food and Drug Officials
2550 Kingston Rd., Suite 311, York, PA 17402
Phone: 717-757-2888/Fax 717-755-8089

SUBMIT ONE COMPLETE APPLICATION FOR EACH COURSE DATE AND LOCATION
Legible and complete applications assure a prompt response!

1. Applicant _____
   Last name First name MI
   Title _____
   Address _____
   Phone _____ Fax _____
   E-mail _____
2. Course (Check one): HACCP 3-day[ ] or SCP 1 –day [ ] or Segment Two 1-day [ ]
   Course Date/Location _____ / _____Expected No. of Students ____
3. Instructors and qualifying credentials. **Attach brief vitae with addresses and communications.**
   Include certificate numbers for all the AFDO/Alliance 'qualified' instructor(s).
   a. *Supervisory Instructor _____
   b. _____
   * Supervisory Instructor must be AFDO 'qualified' according to the AFDO/Alliance Seafood HACCP and SCP Training Protocol and be present for the duration of the course.
4. Course Auditor. **Provide brief vitae with addresses and telecommunications.**
   Organization _____
   Name/Title _____
   Address _____
   Phone (country code/city code)_____/Fax _____
   E-mail _____
5. Explain role of the Course Auditor in governing seafood commerce and processing in the country where course will be taught:
   Will the **Course Auditor** have any role in the training portion of the program?
6. Course outline (submit for review of topics, schedule and instructor assignments). Reference the Basic Course Outline.
7. List training materials to be used in addition to the AFDO/Alliance Core Training Manual and FDA's Hazard Guide for Fish and Fishing Products.
8. Course registration fee: Total Estimate cost/student $ _____
   Registration fee must include:
   1) $30 per HACCP student or $20 per SCP student to AFDO for recording and preparing the AFDO Certificates of Course Completion
   2) $40 for the HACCP or $25 for the SCP training manuals
   3) prepaid course(s) applicant fee ($100).
   Additional Costs/Student includes: (Use additional page if necessary)

Signature of the applicant and/or Supervisory Instructor denoting agreement to conduct the described training in accordance with the AFDO/Alliance Seafood HACCP and SCP Training Protocol and to be responsible for all itemized fees
Name:_____Date _____

CONTACT INFORMATION			
Name:			
Address:			
Telephone:		Cell Phone:	
Fax:		e-Mail:	
OCCUPATION AND EXPERIENCE			
Position Description with relevance to HACCP and Seafood Processing:			
HACCP Experience (Implementation and Training):			
Have you taken the Basic (3-Day) Alliance Seafood Course? ☐ **YES** ☐ **NO**			
References per HACCP and Seafood Processing Experience (Minimum of three(3)):			
Attach Condensed Vitae (maximum 2 pages) to include professional affiliations related to seafood safety, any related publications, training programs or seafood HACCP implementation)			
RESPONSIBILITY AS SEAFOOD HACCP ALLIANCE TRAINER			
By signing this document, I acknowledge that HACCP and related Sanitation Control Procedures courses, in order to be denoted as Seafood HACCP Alliance courses with Association of Food and Drug Officials (AFDO) certification, must comply with the established training protocols. These protocols can be found on the AFDO web site, www.afdo.org, and include prior course approvals, use of core training manuals, standard training formats, and associated registration fees. Any misrepresentation of the protocol, the Alliance or AFDO can result in revocation of the qualified trainer status.			
SIGNATURE			**DATE**
• Trainer applications in the USA should be directed through the regional AFDO Affiliate. • International Trainer applications should be directed through the AFDO headquarters.			

Sanitation Control Procedures
Training Points

Contributors:
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Content:

Chapter 1-Safety of Water

Introduction:

1. Water is of major importance because of its broad use and application in food processing
2. A primary safety concern for any food processing operation should be the safety of water.

Monitoring-Sources:

3. Monitoring of the water source must be done with sufficient frequency to assure that the water is safe for use.

Monitoring-Plumbing:

4. Monitoring should be done for cross connections between potable water lines and non-potable water or sewer lines.

Monitoring-Ice:

5. The safety of ice made from the water supply and its storage and handling conditions should also be monitored.

Corrections:

6. When monitoring detects a problem with the processing water source, corrective action must be taken and recorded on the appropriate Daily Sanitation Control Record.

Records:

7. Records are necessary to document that the processor is conforming to sanitary conditions and practices.

Water Standards:

8. Total coliforms are a useful indicator of potential sewage contamination

In-Plant Water Contamination:

9. May occur from cross connections and backflow problems

Chapter 2: Condition and Cleanliness of Food Contact Surfaces

Introduction:

1. Food contact surfaces are surfaces that contact human food or that drain onto the food, or onto surfaces that contact the food, during normal operations.

Monitoring:

2. Monthly visual inspections are used to ensure that food contact surfaces are in good condition and can be properly cleaned and sanitized.
3. The adequacy of cleaning and sanitizing should be monitored after each cleaning and sanitizing operation.
4. Gloves and aprons should be checked daily for cleanliness and good repair.
5. Sanitizer strength should be checked before the sanitizer is applied.

Verification:

6. Verification checks for sanitation are recommended, but not required.

Corrections:

7. Problems with food contact surfaces that are not easily cleaned should be corrected in a timely manner.
8. Problems with improperly cleaned and sanitized equipment, employee gloves and outer garments, and sanitizer strength should be corrected before work begins.

Records:

9. Monitoring should be more frequent for food contact surfaces associated with ready-to-eat products than for surfaces associated with raw, to-be-cooked seafoods.

Chapter 3: Prevention of Cross-Contamination

Introduction:

1. Cross-contamination occurs when biological, physical, or chemical contaminants are transferred to food products.
2. Key Sanitation Condition No. 3: How does one prevent cross-contamination? By
   a) Employee practices
   b) Physical separation of raw and ready-to-eat foods
   c) Adequate plant design

Monitoring:

2. Check or monitor employees, product, and facilities before work (pre-op), at work (at designated time intervals), and after work (post-op). Examples of what to monitor:
   a) Employee practices:
      i. adequacy and frequency of hand washing
      ii. cleanliness of outer garments
      iii. eating, drinking, smoking
   b) Physical separation of raw and ready-to-eat foods:
      i. adequacy and consistency of separation
      ii. need for footbaths between raw and cooked areas
   c) Adequate plant design:
      i. changes in the plant layout that affect separation of raw from ready- to-eat foods
      ii. changes in the physical condition of the plant

Corrections:

3. Stop, correct, prevent from recurring, evaluate product safety, and document corrections. Some examples are:
   a) Employee practices:
      i. Teach proper hand washing before allowing to work.
      ii. Change outer garments before returning or continuing to work.
      iii. Teach where eating, drinking, smoking may be done.
   b) Physical separation of raw and ready-to-eat foods:
      i. Separate raw and cooked foods. Check product safety.
      ii. Place footbaths between raw and cooked areas. Check product.
   c) Adequate plant design:
      i. If modified plant layout affects the foods, redesign.
      ii. If physical condition of the plant affects the food, improve condition.

Records:

4. Record monitoring results and corrections taken in Daily Sanitation Record. Monitor should initial, record the time, and date of activity. Regularly scheduled monitoring requires records.

Chapter 4: Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities

Introduction:

1. Hand washing, hand sanitizing and toilet facilities are essential parts of the hand washing program in order to prevent cross contamination.

Monitoring:

2. Hand washing, hand sanitizing and toilet facilities should be checked and documented on the Daily Sanitation Control Record at least once per day (preferably during pre-op) for cleanliness, proper function, and adequate supplies; hot water (110° F or 43°C) should be checked weekly.
3. Hand sanitizer concentrations should be checked:
    a. In ready-to-eat food plants at least every 4 hours,
    b. In raw, to-be-cooked seafoods, at least during pre-op check.

Corrections:

4. When monitoring toilet and hand washing facilities indicate that supplies are lacking or they are not functioning properly, fix the problem immediately.
5. When hand sanitizer concentrations are incorrect, a new hand dip with the proper concentrations should be provided and a responsible individual should determine 1) whether employees need to rewash and sanitize their hands, and 2) what to do with the affected product.

Records:

6. The Daily Sanitation Control Record should identify where and when each observation was made, whether the conditions observed were satisfactory or unsatisfactory, actual concentration of any sanitizers observed, any necessary corrections, and the person making the observations.

Background:

7. Hand washing facilities should be solely dedicated for that purpose.
8. The proper hand sanitizing concentration range for chlorine is 100-200 ppm and for iodine is 12.5- 25 ppm.
9. Hand sanitizing facilities should be: conveniently located to encourage employee use, but avoid contact with foods.

Chapter 5: Protection of Food from Adulterants

Introduction:

1. This chapter refers to insanitary preparation, packing, or holding of foods that then become contaminated with filth, poisonous, or deleterious substances (called adulterants).
2. Key Sanitation Condition No. 5: How does one protect food, food packaging, and food contact surfaces from contaminants or adulterants? By monitoring possibility of contamination from:
    a) Toxic compounds (e.g., pesticides, cleaners and sanitizers, fuel, lubricants as discussed in Chapter 6)
    b) Insanitary condensate or standing pools of water

Monitoring:

3. Check for location of hand sanitizing dips that may contaminate food and food contact surfaces through splashing at pre-op or start-up, after every 4 hours, and at post-op.
4. Check for accumulation of condensate on ceiling at pre-op or start-up, after every 4 hours, and at post-op.

Corrections:

5. Stop, correct, prevent from recurring, evaluate product safety, and document corrections. Some examples are:
    a) Relocate hand sanitizing dips to prevent adulteration of food and food contact surfaces by splashing. Check product safety.
    b) Recommend improved ventilation or other measures to stop condensate accumulation. Check product safety.

Records:

6. Record monitoring results and corrections taken in Daily Sanitation Record. Monitor should initial, record the time, and date of activity.

Chapter 6: Proper Labeling, Storage, and Use of Toxic Compounds

Introduction:

1. The improper use of toxic compounds (e.g., cleaners, sanitizers, rodenticides, insecticides, machine lubricants, and some food additives) may lead to product adulteration.
2. Key Sanitation Condition No. 6: Toxic compounds must be properly labeled, stored, and used to prevent contamination of food, food contact surfaces, packaging materials, and ingredients.

Monitoring:

3. Check proper labeling at least once a day. Checking means: a)
    a) If in the original container,
        i. Name of the compound in the container
        ii. Responsibility statement: Manufacturer name and address or second party manufacturer/packer/distributor
        iii. Appropriate approvals (EPA registration) iv)
        iv. Instructions for proper use
    b) If in a working container,
        i. Name of the compound in the container
        ii. Instructions for proper use
4. Check proper storage at least once a day including:
    a) Placing in an area with limited access (e.g., under lock and key given only to certain personnel)
    b) Separating food-grade from non food-grade materials (original containers are useful)
    c) Keeping away from food, food contact surfaces, packaging materials, and ingredients
    d) Using food containers ONLY for food
5. Check proper use at least once a day including:
    a) Following the manufacturer's instructions or recommendation and as provided on the EPA registered label
    b) Using in a manner that will not result in food adulteration

Corrections:

6. If original container is improperly labeled, set aside and return supplies to the supplier at a timely fashion. If working container is improperly labeled, replace with proper labels immediately. If working container is inappropriate or damage, destroy or discard container immediately.
7. If chemicals are improperly stored, move to proper storage location immediately.
8. If chemicals are improperly used, immediately assign other previously trained employees to use the chemicals then retrain those who were not using them properly.

Records:

9. Record monitoring results and corrections taken in Daily Sanitation Record. Monitor should initial, record the time, and date of activity.

Chapter 7: Control of Employee Health Conditions

Introduction:

10. Employee health and hygiene are major components of a company's sanitation control program.

Monitoring:

11. Monitoring employees for symptoms of illness and for wounds that could potentially contaminate food should be observed during pre-op or at the start of each shift.
12. Because a person's health can change over night, it is important to monitor employee health on a daily basis.
13. Employees must report if they have a diagnosed illness, a symptom or a high-risk condition.

Corrections:

14. If an employee has symptoms of a disease or infection that could contaminate food products, supervisors should (depending on the situation) reassign, relocate, send home, or require that an impermeable cover be placed over lesions.

Records:

15. All unsatisfactory conditions must be recorded with the corrective action taken to reduce or eliminate the problem.

Background:

16. Emphasize to employees that any of these signs or symptoms (diarrhea, vomiting, open skin sores, boils, fever, dark urine or jaundice) may indicate infection by a pathogen that can be transmitted to others through food handling.

Management Responsibilities:

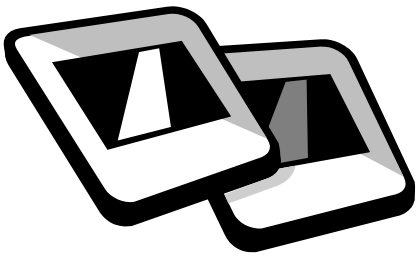
17. Management should have a written health policy that requires reporting, work restrictions and exclusions for employees who have symptoms or high-risk conditions.

Personnel Responsibilities:

18. Employees should practice good hygiene and report any illness or lesions to the supervisor before working with food.

HACCP Train-The-Trainer Presentation

Slides



Slide 1

Chapter 1: Introduction to Course and HACCP

Slide 2

Objectives: In this module you will learn the:

- Objective of the course
- Format of the course
- Format of the course
- Expectations of the participant
- Meaning and importance of HACCP

Slide 3

Instructor responsibilities

- Must use the required text
- Students must be provided blank forms
- Use audio visual materials designed for class (PP slides) can be downloaded from net
- Use flip charts, erasable boards or overhead projector as required
- Extra curricular activities and presentations should be presented during breaks or lunch

Slide 4

Instructor responsibilities

- Relate HACCP concepts to products produced by participants where possible
- Must follow the requirements of the AFDO protocol
- Must ensure a proper learning environment

Slide 5

Classroom

- Conducive to learning (lighting, noise, restrooms, desks, chairs, accessibility and security)
- Plan for the breakout rooms
- Be prepared! Equipment should work, student sign-in, materials distributed, and be there early
- Provide name cards

Slide 6

Convening Class

- The opening of class sets the tone for the entire class
- Introduce yourself and have class quickly introduce themselves
- Provide ground rules for the class: logistics for breaks and lunch, emergency information and exits in case of fire or emergency, turn off cell phones, class attendance requirements, etc.

Slide 7

Convening Class

- Before starting instruction, make sure all students have manuals and materials
- Careful explain the purpose of the class and who is required to attend. Explain the definition of a processor.
- Ask if there are any questions

Slide 8

Overview of the Class

- Three segments: HACCP fundamentals, regulations and work session
- Encourage class participation and contributions
- Become familiar with the manuals and the use of them

Slide 9

Meaning and importance of HACCP

- Give basic information, what HACCP stands for, history, etc.
- Briefly cover the seven principles of HACCP
- Explain the difference between a traditional inspection and a HACCP inspection

Slide 1

Chapter 2

Hazards –
Biological, Chemical
and Physical

Slide 2

Learning Objectives and Opportunities:

- **To introduce and give background on food safety hazard that can be found in seafood products**
- **This chapter provides the initial opportunity to engage and involve the course participants – set the stage and course "norm" for active involvement and exchange.**

Slide 3

Learning Objectives and Opportunities:

- **Many opportunities for Q&A with the students – start with simple examples of hazards and ask related questions.**
- **REMEMBER, this section is given the longest time allotment in the course. Engage the class and develop discussion. Issues, concerns, misconceptions, guidance discussed at this stage of the course will help to broaden and deepen the understanding of HACCP**

Slide 4

Materials and Visual Aids:

- Surfaces and supplies to write and present suggestions and examples from and to the class participants
  - Flip Chart
  - Dry erase board
  - Chalk board
  - Overhead Transparency
- Use a local seafood product and process as an example to generate hazard identification and discussion

Slide 5

Key Teaching points:

- Introduce the three classes of hazards (biological, chemical and physical) and how they differ from each other.
  - Living
  - Chemical (why is histamine a chemical hazard and not biological?)
  - Mineral

Slide 6

Key Teaching points *continued:*

- Define the concept of a hazard
  - conditions not directly related to the safety of the food
- Emphasize the difference between hazards under HACCP and non-hazard issues of concern
  - Sanitation/GMPs
  - Quality
  - Profitability
  - Economic Fraud

Slide 7

Key Teaching points *continued:*

- **For the three classes of Hazards:**
  - **Discuss how the hazards occur in the environment**
  - **Discuss factors which contribute to their role as a hazard**
  - **Discuss control methods to render the product safe**
- **Present a variety of Examples**

Slide 8

Key Teaching points *continued:*

- **Biological hazards (bacteria, viruses and parasites)**
- **Emphasize microorganism growth requirements**
  - This concept is **KEY** - more important than covering each organism in detail or memorizing the different pathogens.
  - Note difference between pathogens and spoilage organisms.
- **Discuss food borne illness symptoms, and methods to control microorganisms**.

Slide 9

Key Teaching points *continued:*

- **Introduce the three categories of chemical hazards**
  - **naturally occurring, ie allergens**
  - **intentionally added**
  - **unintentionally or incidentally added**
- **Examples are given**
  - **In text and listed in Table B**
  - **Introduce sulfite as a hazard**
    - Commercial processing example
- **Identify and link chemical sources and practices that connect the hazard to the food product**

Slide 10

Key Teaching points *continued:*

- Discuss why given chemical examples are a hazard.
  - Toxic
  - Allergen
  - Illegal
- Emphasize histamine and ciguatera fish poisoning, and other potential examples common to seafood processing sectors in your area and participants.

Slide 11

Key Teaching points *continued:*

- Introduce physical hazards
- Give examples
  - Describe potential harm that may result
  - Describe control methods
- This section is a good opportunity for class discussion
- Introduce and discus the concept of ambiguity between hazard and quality or sanitation
  - Bones , shell pieces
  - Safety? Quality?

Slide 12

Summary

- Upon completion of the chapter, the participants should be able to:
  - Differentiate between hazards and GMPs,
  - Identify characteristics of the three hazards (biological, chemical and physical)
  - Understand the importance of cause and control of the hazards

Slide 1

Chapter 3

Prerequisite Programs
and
Preliminary Steps

Slide 2

Learning Objectives:

- **Explain the pre-requisite programs including GMPs, sanitation, product controls, traceability, recalls etc. that provide the foundation for HACCP**
- **Introduce the preliminary (information gathering) steps that need to be completed before you can start the Hazard Analysis.**

Slide 3

Teaching points:

<u>Part 1 – Prerequisite Programs</u>

- **Define and contrast programs focused on operational conditions (e.g. GMPs) vs. specific food safety hazards (e.g. HACCP controls for histamine)**
- **Give examples of pre-requisite programs: GMPs, sanitation, personnel policies, employee training, product tracking, recall procedures, consumer complaints etc.**

Slide 4

Teaching points continued:

Good Manufacturing Practices

- **The regulation that describes what conditions and practices are necessary for the safe handling of food. Give citation (Part 110 of 21 CFR) and where to find a copy**
- **General description of what is included in GMPs:**
  - **Facilities, equipment and grounds**
  - **Water, plumbing and waste disposal**
  - **Cross contamination prevention**
  - **Food processing and storage controls**
  - **Protection of food from adulterants**
  - **Proper cleaning & sanitizing**
  - **Employee health and hygiene**

Slide 5

Teaching points continued:

GMPs vs SSOPs

- **GMPs - describe the general conditions & practices necessary for the safe handling of food.**
- **SSOPs – describe the specific procedures used to meet each GMP condition including what will be done, who will do it, when and where it will be done, and how success will be monitored**

Give examples to illustrate (e.g.):

GMP – No pests in food handling area

SSOP – Describe the firm's pest control program, what checks are made daily, where checks are made and who does them, what corrections are taken when problems are observed

Slide 6

Teaching points continued:

GMPs & The FDA Seafood HACCP Regulation

- **Describe sanitation requirements (Section 123.11) of the FDA Seafood HACCP regulation**
- **Processors should have a written SSOP**
- **Processors shall monitor and maintain records of results & corrections for 8 areas of sanitation:**

1. **Safety of water**
2. **Condition & cleanliness of food contact surfaces**
3. **Prevention of cross contamination**
4. **Maintenance of hand washing & toilet facilities**
5. **Protection of food from adulteration**
6. **Proper labeling, storage & use of toxic materials**
7. **Control of employee health**
8. **Exclusion of pests**

Slide 7

Teaching points continued:

GMPs & The FDA Seafood HACCP Regulation

- **Review daily sanitation monitoring records from Encore training course manual or SCP manual as appropriate**
- **Describe Alliance Sanitation Control Procedures (SCP) course and training manual**
- **Describe other worker training resources as appropriate for GMPs**

Slide 8

Teaching points continued:

Briefly describe other types of Prerequisite Programs For example:

- **Employee personnel and performance policies**
- **Worker training programs**
- **Compliance programs & licenses for state and local regulatory requirements**
- **Product coding, traceability, & recall systems**
- **Supplier controls & product specifications**
- **Standard Operating Procedures for routine operations**
- **Consumer complaint procedures**

Slide 9

Teaching points:

<u>Part 2 – Preliminary Steps</u>

- **Preliminary Steps involve gathering the information that is needed to apply the first HACCP Principle and conduct a Hazard Analysis including:**

  - What products are to be included
  - What process steps these products undergo
  - How these products will be used
  - Who will conduct the Hazard Analysis & develop the HACCP Plan

Slide 10

Teaching points continued:

Preliminary Step

Define the products to be included in the Hazard Analysis:

- **Make a list of all fish & shellfish species handled**
  (Refer to Tables 3-1 & 3-2 in FDA Hazards Guide)
  and
- **Identify all of the product forms used for each species**
  (Refer to Table 3-3 in FDA Hazards Guide)
  and
- **Identify how each product is stored, packaged & distributed**
  (Refer to Table 3-3 in FDA Hazards Guide)
  and
- **Likely customers (general public vs. special groups)**
  and
- **Intended Use (cooked before consumed vs. eaten raw)**

Slide 11

Teaching points continued:

Preliminary Step

What process steps are conducted:

- **Describe how to develop a Process Flow Diagram & Give an Example: Receive Products**
  ↓
  Store Products
  ↓
  Process Products
  ↓
  Package Products
  ↓
  Ship Products
- **Describe how to verify that a Flow Diagram is accurate and complete**

Slide 12

Teaching points continued:

Preliminary Step

Decide Who will be on the Team to conduct the Hazard Analysis and write the HACCP Plan:

Consider: who will contribute to accuracy of plan; who will be involved in the implementation of the plan; who will be involved in routine plan activities etc.

Slide 13

Materials and aids:

- Selected overheads from the Alliance Sanitation (SCP) course – GMP/HACCP pyramid; 8 areas of sanitation; sanitation monitoring forms etc.
- Supplemental overheads of GMP vs SSOP examples as appropriate.
- Supplemental information, handouts or resources related to 8 areas of sanitation or GMPs.
- Overheads illustrating worksheets and other tools from the Wholesale/Distribution/Warehouse model (Appendix 5) or the Alliance Encore course to illustrate how to compile a complete list of species and product forms or types.

Slide 14

Chapter 4

Commercial Example

ABC Shrimp Company

Slide 15

Learning Objectives:

- The purpose of this Chapter is to introduce a fictional company and its process that will be used as the example to illustrate each HACCP Principle in the subsequent chapters.
- A secondary objective of this Chapter can be to illustrate the types of information that would be compiled in the preliminary steps and what a firm's written SSOP for the 8 areas of sanitation and monitoring forms might look like.

Slide 16

Teaching points:

Part 1 – Introduce ABC Shrimp Co.

- **Explain the concept of a process narrative and how it relates to the preliminary steps**
- **Briefly describe each process step using the company's flow diagram as an overhead**

Slide 17

Teaching points:

Part 1 – Introduce ABC Shrimp Company's Process

Tips/Points to Emphasize:

- **Two different types of raw material (fresh have sulfites & frozen has no sulfites)**
- **Describe next 6 steps (grading through cull table) together as a rapid automated process**
- **Focus on cooking step and the need to establish a scientifically justified cooking procedure**
- **Describe next 6 steps (shuffler thru glaze) together as a rapid automated process**
- **Emphasize Weigh/Pack/Label**

Slide 18

Part 2 – Introduce ABC Shrimp Company's SSOP

Tips/Points to Emphasize:

- **That the written SSOP (p. 39-46) covers the 8 areas of sanitation in FDA's regulation**
- **Describe the format of the SSOP**
  - **The Sanitation Condition being Addressed**
  - **Controls Used**
  - **Monitoring Procedures**
  - **Corrections**
  - **Records**
- **Suggest that students review each specific written SSOP on their own**
- **Review the concept of daily and periodic sanitation monitoring forms and review the example provided in the manual using an overhead of Table 2 and Table 3.**

Slide 19

Summary

Use Chapters 3 and 4 to make sure that:

- Students understand the pre-requisite programs that provide the foundation for HACCP
- Students understand what the GMPs are and the 8 areas of sanitation included in the FDA regulation
- Students understand the difference between GMPs and SSOPs
- Students understand how to develop SSOPs and routine monitoring and records
- Students understand how to complete the preliminary steps before they can apply the 1st HACCP principle and begin the Hazard Analysis
- Students have a basic awareness of the process example (ABC Shrimp Co.) which will be used in subsequent chapters

Slide 1

Chapter 5: Principle 1: Hazard Analysis

Slide 2

Objectives: In this module you will learn:

- **What hazard analysis is**
- **How to conduct a hazard analysis**
- **How to identify significant hazards**
- **What control measures are**
- **How to identify control measures**

Slide 3

<u>Visual Aids and References</u>: Provide and make available to all students the following:

- **Blank copies of the "hazard analysis forms"**
- **FDA's Hazards Guide**

Slide 4

Visual Aids and References: Use the following to assist in teaching the principle:

- **Blank transparencies of the "hazard analysis forms" and an overhead to project**
- **Easel, flip chart or erasable board**

Slide 5

One of the most difficult HACCP steps

- **Must be science-based**
- **Emerging hazards must be considered (updates critical)**
- **Students should not confused hazards with food quality issues**
- **Used all available sources of acceptable information**

Slide 6

Explain the "Hazard Analysis Worksheet"

- **All students should have blank copies of the form prior to instruction of the Chapter. Hand out at the beginning the discussion.**
- **Take a few minutes to go over the form and explain each column.**
- **Explain that this form is a tool for developing a HACCP plan. It is not required by FDA but could be shared with FDA.**

Slide 7

Using the "Hazard Analysis Worksheet"

- **Column one: Each processing step identified in the flow diagram (Chapter 3) is listed (one step per block)**
- **Column two: Correctly identifying food safety hazards is key to success. Follow the recommended process.**

Slide 8

Column Two exercise:

- **Quickly review the three categories of hazards.**
- **Use the Shrimp example in the book or chose another seafood product for the exercise if more suitable for the audience.**
- **Have a flow diagram of the process in view of the class (on board or overhead). Have the class quickly help develop one for the purposes of this exercise.**

Slide 9

Column Two exercise:

- **Select the receiving step for discussion**
- **Without referencing any source of information, have the class list all possible hazards associated with the receiving step. It may be beneficial to ask the question "If you were to eat this seafood at this step, is there anything in the product that could make you sick?"**

Slide 10

Column Two exercise:

- **Write all suggested hazards on the board or overhead. Let the class make the suggestions, don't spoon feed but have them think and respond. You should get answers like dirt, grass, bacteria, fuel, shell, etc. Don't discourage any answer.**

Slide 11

Column Two exercise:

- **When you list ten or more responses, explain that the class will conduct the hazard analysis, asking the following questions for each potential hazard listed to determine if it is a true hazard (overhead 5):**
  - **Reasonable likely to occur?**
  - **Likely to result in an unacceptable risk to consumers**

  A "yes" to both questions would determine a significant hazard, all other answered would be removed.

Slide 12

Column Two exercise:

- **List all identified hazards in Column 2**
- **Complete columns 3 – 5 (self explanatory)**
- **Emphasize that the answers in Column 6 will be used as a foundation for developing HACCP plans**

Slide 13

Control Measures:

- Explain some of the more common control measures used in seafood processing with specific examples (temperature, water activity, pH, etc.) in relation to the three categories of hazards
- If possible, show some examples of equipment used to measure these control measures

Slide 1

Chapter 6

Principle 2:
Determine the
Critical Control Points

Slide 2

Learning Objectives and Opportunities:

- **Linking the hazard analysis exercise to the actual HACCP plan**
- **Understanding of concept of "critical" nature of control point to food safety control and HACCP**
- **Determination of CCPs**

Slide 3

Learning Objectives and Opportunities:

- **Understanding the difference between a CCP and a Control Point in HACCP parlance**
- **Emphasizing that the correct identification and determination of the CCPs is necessary to complete the required HACCP plan.**

Slide 4

Materials and Visual Aids:

- **Continue the use of the "hazard analysis forms" handed out during the previous chapter**
- **FDA's Hazards Guide**

Slide 5

Key Teaching points:

- **Clearly define and explain the concept of a "Critical Control Point"**
  - **Emphasize understanding that a CCP is a point or step in the process where control is applied**
  - **The CCP is determined from a process step listed on the hazard analysis worksheet**
  - **Not necessarily only time and temperature**

Slide 6

Key Teaching points *continued:*

- **Emphasize that for every significant hazard identified during the hazard analysis, there must be at least one step in the process where the hazard will be controlled.**
  - **Sometimes more than one hazard controlled with one CCP**
  - **Sometimes more than one CCP needed to control a hazard**

Slide 7

Key Teaching points *continued:*

- **Emphasize that hazards can be controlled by:**
  - **Prevention**
  - **Elimination**
  - **Reduction to an acceptable level**
- **Important concept**
  - **Examples given in the training curriculum**
  - **Others from your experience**
- **Ask students to identify examples in each category**

Slide 8

Key Teaching points *continued:*

- **Distinguish between a CCP and Control Point**
  - **Emphasize that CCPs are only for controlling a food safety hazard**
  - **Control Point important for quality and other concerns, but not HACCP**
- **Emphasize a simple HACCP plan**
  - **No more CCPs than necessary!**

Slide 9

Key Teaching points *continued:*

- **Emphasize that the CCPs are product AND process specific**
- **Discuss how changes to product integrity or process equipment require renewed hazard analysis and potential changes to the resulting HACCP plan.**

Slide 10

Key Teaching points *continued:*

- **Introduce the CCP Decision Tree Table**
  - **Explain its use to identify CCPs and finish the hazard analysis for the commercial process shrimp example**
  - **Emphasize that it is only ONE tool that can be used to help identify CCPs**

Slide 11

Summary

- **Upon completion of the chapter, the participants should be able to:**
  - **Identify and determine CCPs**
  - **Know that once a food safety hazard has identified, a CCP will be required to control the hazard**
  - **Understand that there are three ways a hazard can be controlled**

Slide 12

Summary

- **Upon completion of the chapter, the participants should be able to:**
  - **Distinguish between a CCP and Control Point**
  - **Know that correct determination of CCPs are critical to developing a valid HACCP plan**

Slide 1

Chapter 8: Principle 4: Critical Control Point Monitoring

Slide 2

Objective: In this module, you will learn:

- How monitoring is defined
- Why monitoring is needed
- How to design a monitoring system
- What methods and equipment are used for monitoring critical limits
- How often monitoring should be performed
- Who should monitor

Slide 3

Visual Aids and References:

- Static display or pictures of monitoring equipment
- List of companies or web pages that provide monitoring equipment
- Demonstration on the use of common monitoring equipment

Slide 4

This Chapter provides an opportunity to discuss technical data collection with processors

- Processors are generally interested in the topic
- Many have had extensive experience working with food processing instruments
- Excellent opportunity to discuss with processors

Slide 5

Purpose of Monitoring

- Maintain control of a CCP
- Must be accurate. The monitoring will only be as good as the instrument is accurate
- Records are produced as a result of monitoring correctly
- Give some examples of equipment not providing accurate information and the potential consequences (You can not assume that monitoring instruments are accurate)

Slide 6

Design of a monitoring system

- Talk about designing the system in terms of the HACCP plan: What, How, Frequency and Who
- Good idea to review the HACCP plan columns before discussion of each

Slide 7

What?

- **Specific examples such as temperature, water activity, time, etc.**
- **In some cases, it may not be data but certifications, letters of compliance, etc.**

Slide 8

How?

- **Emphasize the differences between laboratory testing and "real time" data collection and use some examples (lab results take time, effectiveness, etc)**
- **Discuss some monitoring devices and accuracy considerations, i.e., if device is accurate only 2 degrees then always up critical limit by that margin of safety.**

Slide 9

Frequency?

- **This topic should invite quite a bit of discussion. Processors want to know what recommended (continuous). Discuss continuous vs. periodic.**
- **Determining frequency of monitoring is a matter of risk. Use examples of expensive seafood that may have to be destroyed. The longer the frequency, the greater the loss**

Slide 10

WHO?

- **Needs to be a key individual**
- **Should have proper training and technical understanding**
- **Should have authority to sign records**

Slide 1

Chapter 9: Principle 5: Corrective Actions

Slide 2

Objective: In this module, you will learn:

- **The definition of corrective actions**
- **Procedures for corrective actions**
- **Record-keeping requirements for corrective actions**

Slide 3

Visual aids

- **Blank copies of Corrective Actions records**
- **Examples of monitoring records which have process deviations on them (could be on overhead for class to examine and determine deviations)**
- **Flip chart, erasable board, and/or overhead with transparencies**

Slide 4

Corrective Action Procedures

- Encourage discussion among class to identify possible corrective actions to be taken in the event of a CCP process deviation (product disposition).
- Work into the conversation that all corrective actions must be documented.

Slide 5

Components of Corrective Actions

- The following two components (overhead 4) must be emphasized. Providing some "what ifs" situations would be useful.
  - Correct and eliminate the cause of the deviation and restore process control
  - Identify the product that was produced during the process deviation

Slide 6

Correct and eliminate the cause of the deviation and restore process control

- Students need to appreciate both short term and long fix of the problem
- The long term solution may be rewriting the HACCP plan

Slide 7

Identify the product that was produced during the process deviation

- **Disposition of product where a process deviation has occurred is key to this module. A thorough discussion of the issue should be initiated with students.**
- **Discuss the four steps in Overhead 5.**

Slide 8

Teaching points:

- **Go through the "If/Then" format with students. Stress the importance of determining the "If/Then" scenarios associated possible deviations within their own facilities.**
- **Develop a model corrective action record with students on a flip chart or board. Once students develop it, show the model corrective action record and compare.**

Slide 1

Chapter 11: Principle 7: Record-Keeping Procedures

Slide 2

Learning Objectives:

1. What kinds of records are needed in a HACCP system
2. When to record monitoring information
3. How computerized records can be used
4. How to conduct a record review

Slide 3

Learning Objectives II:

In addition, the learner will be able to identify and comply with:

- *General requirements*
- *Record retention*
- *Official review*
- *Who signs and dates the HACCP plan*
- *How often the HACCP plan is reviewed*
- *The English requirement for records*

Slide 4

Materials and aids:

- **Contents in the training curriculum:**
  - **Ch. 3: Prerequisite Program (re: sanitation) p. 29 and p. 139 (overheads 23-24)**
  - **Ch. 9: CA record requirements p. 95**
  - **Ch. 10: Record review p. 103-107**
  - **Ch. 11: Principle 7 p. 111-126**
    - **Examples of records p. 116-124**
    - **ABC Shrimp HACCP plan form p. 125-126**
  - **Ch. 12: Seafood HACCP regulation p. 132-144 (Overheads: 11-13, 18-24, 27, 35)**

Slide 5

Materials and aids:

- **Contents in the training curriculum (contd.):**
  - **Appendix 1: FDA's Seafood HACCP Rule p. 155-170**
  - **§ 123.6b and c (7) HACCP plan and record keeping**
  - **§ 123.7d Corrective action records**
  - **§ 123.8d Verification records**
  - **§ 123.9 Records**
  - **§ 123.11c Sanitation Control Procedures**
  - **§ 123.12c Special Requirements for Imported Products, Records**
  - **§ 123.28c Raw molluscan shellfish**
  - **§ 123.28d Shucked molluscan shellfish**

Slide 6

Materials and aids:

- **Props:**
  - **Labeled folders:**
    - **HACCP plan and support documentation**
    - **CCP monitoring records**
    - **Corrective action records**
    - **Verification activities records**
    - **SSOP - 8 key sanitation conditions and practices**
    - **SSOP - correction records**
  - **Records (HACCP, CA, CCP monitoring, and verification)**
  - **Rubber stamp and stamp pad for signing and dating reviewed records**
  - **Treats (small candies, pencils, etc.)**

Slide 7

Teaching points:

1. Review and distinguish the 4 categories of HACCP records kept

- **HACCP Plan and Support Documentation**
  - **Sanitation control records**
  - **Sanitation correction records**
  - **Adequacy of equipment or processes**
  - **Results of scientific studies and evaluations**
  - **Hazard Assessment, flow chart, processing narrative**
- **CCP Monitoring Records**
- **Corrective Action Records**
- **Verification Records**

Slide 8

Teaching points:

- **HACCP Plan** p. 122

Shall:

- **List food safety hazards that are reasonably likely to occur**
- **List CCPs**
- **List critical limits**
- **List monitoring procedures**
- **List predetermined CA plans***
- **List verification measures**
- **Provide for a system of monitoring records**

*** Predetermined CAs are not required**

Slide 9

Teaching points:

- **HACCP Plan** p. 160, 161

Shall be signed and dated

- **Upon initial acceptance**
- **Upon any modification***
- **At least annually***
- **By the most responsible individual at the processing facility or a higher level official of the processor**

***Verification requirement**

Slide 10

Teaching points:

- **HACCP Plan and Support Documentation** p. 112
  - Data to develop the HACCP plan (hazard analysis worksheet, flow diagram, processing narrative, etc.)
  - Data to verify adequacy of heat process
  - HACCP team and responsibilities
  - Prerequisite programs (GMPs, SSOPs, product specs, traceability, recall procedures, personnel policies, etc.)
  - Correspondence with experts

Slide 11

Teaching points:

- **HACCP Plan and Support Documentation** p. 29 (overhead 4)

8 Key sanitation conditions and practices:

1. Safety of water
2. Condition and cleanliness of food-contact surfaces
3. Prevention of cross-contamination
4. Maintenance of hand-washing, hand-sanitizing and toilet facilities
5. Protection from adulterants
6. Labeling, storage and use of toxic compounds
7. Employee health conditions
8. Exclusion of pests

Slide 12

Teaching points:

What is a critical control point (CCP)?

A step at which control can be applied and is essential to prevent or eliminate a food-safety hazard or reduce it to an acceptable level – p. 61

What is a critical limit (CL)?

A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food-safety hazard - p. 73

Slide 13

Teaching points:

- **CCP Monitoring Records**
  - amount of decomposition at receiving
  - certificate of INAD usage
  - data logger
  - grower's drug usage records
  - time and temperature:
    - harvest vessel, cook, chill, line speed, smoking, brining
  - supplier's certificate or guarantee
  - molluscan shellfish harvest tag
  - nitrite
  - ph (4.6 or below)
  - production
  - receiving record
  - salt: brine/acid strength, salometer, water phase salt %
  - water activity (A_w below 0.85)

Slide 14

Teaching points:

What is a corrective action?

Procedures to be followed when a deviation occurs – p. 91

Slide 15

Teaching points:

- **Corrective Action Records** p. 95

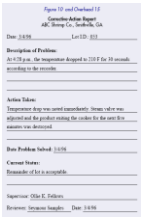
The CA report should contain:

a. Product identification (e.g., description, amount on hold)
b. Description of the deviation
c. CA taken including final disposition of the affected product
d. Name of the individual responsible for taking the correction action
e. Results of the evaluation when necessary

Slide 16

Teaching points:

- **Corrective Action Records** p. 123



Slide 17

Teaching points:

What is verification?

Those activities, other than monitoring, that determine the validity of the HACCP plan and that verify the system is operating according to the plan - p. 99

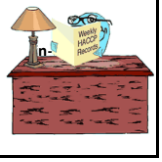
Name some verification activities

- Calibration
- Calibration record review
- Targeted sampling and testing
- CCP record review
- HACCP plan reassessment
- Initial HACCP plan validation
- Subsequent HACCP plan validation
- Corrective action record review

Slide 18

Teaching points:

- **Verification Records** p. 113
  - **Modifications to the HACCP plan**
  - **Processor audit records**
  - **Verification of the accuracy and calibration of all monitoring equipment**
  - **Results of microbiological environmental tests; inspections and equipment evaluation tests**



Slide 19

Teaching points:

- **Verification Records** p. 113

  - **Temperature distribution studies for thermal processes**
  - **Metal detector challenges**

Slide 20

Teaching points:

2. When to record monitoring information p. 114

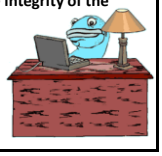
- **Monitoring information shall be entered on records at the time the observation is made.**
- **False or inaccurate records filled out before the operation takes place or ones that are completed later are inappropriate for a HACCP system.**

Slide 21

Teaching points:

3. How computerized records can be used p. 113

- **Include controls to ensure that records are authentic, accurate and protected from unauthorized changes**
- **These records must also ensure the integrity of the electronic data and signatures**



Slide 22

Teaching points:

3. How computerized records can be used

http://www.fda.gov/ora/compliance_ref/part11/Default.htm

Slide 23

Teaching points:

4. How to conduct a record review p. 113-114

- CCP and CA record reviews shall occur within 1 week of the day that the records are made.
- Verification record reviews shall occur within a reasonable time after the records are made.
- All records should be signed or initialed and dated by the reviewer.
- The reviewer shall check that all records include:
  - name and location of the processor or importer
  - Date and time of the activity that the record reflects
  - Signature or initials of the person performing the operation
  - Where appropriate, the product identity and product code (if any).
  - Processing and other information shall be entered on records at the time that it is observed.

Slide 24

Teaching points:

4. How to conduct a record review

p. 105 (overhead 13)

- Monitoring activities have been performed at the locations and frequencies specified in the HACCP plan
- CAs have been performed whenever monitoring indicated deviation from critical limits
- Equipment has been calibrated at the frequencies specified in the HACCP plan.

Slide 25

Teaching points:

- **General Requirements 21 CFR 123.9** p. 163

1. **Name and location of processor or importer**
2. **Date and time of the activity that the record reflects**
3. **Signature or initials of the person performing the operation; and**
4. **Where appropriate, the product identity and production code, if any. Processing and other information shall be entered on records at the time that it is observed.**

Slide 26

Teaching points:

- **Record Retention** p. 163

1. **All required HACCP records for refrigerated products shall be retained at the processing facility or importer's place of business in the US for at least 1 year after the date they were processed**
2. **For frozen preserved or shelf-stable products, 2 years**

Slide 27

Teaching points:

- **Record Retention** p. 163

- **Records related to the general adequacy of equipment or processes (includes scientific studies and evaluations) shall be retained in the US for at least 2 years after their applicability to the product being produced at the facility.**

Slide 28

Teaching points:

- **Record Retention** p. 163

- **If the processing facility is closed for a prolonged period between seasonal packs, or if large 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.**

Slide 29

Teaching points:

- **Official Review** p. 163

All required records, plans and procedures shall be available for official review and copying at reasonable times.

Slide 30

Teaching points:

- **Special Requirements for Imported Products**

- **Affirmative action steps may include:**
  - **Maintaining on file a copy, in English of the foreign processor's HACCP plan, and a written gurantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;**
- **Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps (and subject to provisions of §123.9)**

Slide 31

Teaching points:

Review examples of records p. 116 -126

1. **Monitoring Records – figures 1-4**
2. **Verification Records – figures 5-9**
3. **Corrective Action Record – figure 10**
4. **HACCP Plan Form (review addition of required records to column 10) p. 125 - 126**

Slide 32

Teaching points:

Review examples of records p. 116

Slide 33

Teaching points:

Review examples of records p. 117

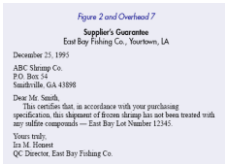


Figure 2 and Overhead 7

Supplier's Guarantee
East Bay Fishing Co., Yourtown, LA

December 25, 1995

ABC Shrimp Co.
P.O. Box 54
Smithville, GA 43898

Dear Mr. Smith,
This certifies that, in accordance with your purchasing specification, this shipment of frozen shrimp has not been treated with any sulfite compounds — East Bay Lot Number 12345.

Yours truly,
Ira M. Honest
QC Director, East Bay Fishing Co.

Slide 34

Teaching points:

Review examples of records p. 117

Figure 3 and Overhead 8

Shrimp Cooker Log
ABC Shrimp Co., Smithville, GA

Date: 3/4/96 Critical Limits: ≥ 212 F for ≥ 3 minutes
Line: Number 1 Product: IQF cooked shrimp
Operator: Jamie Good

Line Number	Lot Number	Time of Day	Steam Temp. (F)	Temp. from Recorder (F)	Cook Time (Min.)	Critical Limits Met	Comments
1	[illegible]	2:34 p.m.		214	3.2	Yes	
1	[illegible]	3:30 p.m.		214	3.2	Yes	
1	[illegible]	4:28 p.m.		**210**	3.1	No	See corrective actions
1	[illegible]	4:29 p.m.		212		Yes	Steam valve adjusted
1	[illegible]	5:01 p.m.	213	212	3.1	Yes	

Temperature/time to be checked hourly during operation.

Reviewer:____________ Date: ____________

If critical limits are exceeded, notify the shift supervisor, and separate and identify the batch involved.

Slide 35

Teaching points:

Review examples of records p. 118

Figure 4 and Overhead 9

Pack-Room Inspection Record
ABC Shrimp Co., Smithville, GA

Date: 3/4/95
Line: Number 1 Product: IQF cooked shrimp
Label Room Supervisor: Betty Smith

Lot Number	Time of Day	Presence of Sulfiting Agents Yes/No	Sulfite Statement on Label Yes/No	Label Type & Comments
043	3:45 p.m.	Yes	Yes	ABC 8 oz.
044	4:45 p.m.	Yes	Yes	Smith Brothers 12 oz.

Reviewer:____________ Date of Review:____________

***Critical Limits:** All shrimp treated with sulfiting agents must be accurately labeled.*

Slide 36

Teaching points:

Review examples of records p. 118

Figure 5 and Overhead 10

A-One Laboratory Report for:
ABC Shrimp Co., Smithville, GA

Date: 3/5/95 Sample Number: ABC Shrimp lot# 002
Vendor: East Bay Sulfites, ppm: < 10 ppm
Examined by: Sheila Good
Remarks:
The above sample was analyzed for the presence of sulfites using official AOAC recognized methods.

Irvine R. Wright
Laboratory Director
A-One Laboratories
Jonestown, PA 25418

Slide 37

Teaching points:

Review examples of records p. 119

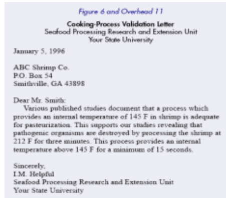


Figure 6 and Overhead 11

Cooking-Process Validation Letter
Seafood Processing Research and Extension Unit
Your State University

January 5, 1996

ABC Shrimp Co.
P.O. Box 54
Smithville, GA 43898

Dear Mr. Smith:

Various published studies document that a process which provides an internal temperature of 145 F in shrimp is adequate for pasteurization. This supports our studies revealing that pathogenic organisms are destroyed by processing the shrimp at 212 F for three minutes. This process provides an internal temperature above 145 F for a minimum of 15 seconds.

Sincerely,
I.M. Helpful
Seafood Processing Research and Extension Unit
Your State University

Slide 38

Teaching points:

Review examples of records p. 120

Figure 7 and Overhead 12

Cooking-Equipment Validation Letter
Seafood Processing Research and Extension Unit
Your State University

January 5, 1996

ABC Shrimp Co.
P.O. Box 54
Smithville, GA 43898

Dear Mr. Smith:

On Dec. 20, 1995, during a visit to your firm, temperature distribution tests were performed in your shrimp steam cooker on line number one using a portable data logger and 12 thermocouple leads. Test results from three production runs indicated that the temperature distribution in your steam cooker, when operated at a mercury-in-glass reading of 212 F, ranges from 212 F to 214 F. These studies indicate that your steam cooker continues to operate as designed.

On this same date, the internal temperature of six shrimp from individual lots of large (3.5 to 5.0 shrimp per oz.), medium (5.0 to 9.0 shrimp per oz.) and small (9.0 to 17.0 shrimp per oz.) shrimp were measured in the cooker during production runs at 212 F for three minutes. The internal temperature of the large shrimp exceeded 150 F; the medium shrimp, 160 F; and the small shrimp, 165 F. The internal temperatures noted during these tests exceed your firm's HACCP critical limits of an internal temperature of 145 F for 15 seconds.

Sincerely,
I.M. Helpful
Seafood Processing Research and Extension Unit
Your State University

Slide 39

Teaching points:

Review examples of records p. 121

Figure 8 and Overhead 13

Equipment-Calibration Log
Temperature Measurement
Instrument/Equipment
ABC Shrimp Co., Smithville, GA

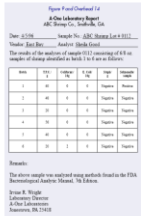
Instrument/Equipment: Standard thermometer
Location in Plant: Shrimp Cooker Line Number One
Serial Number: B566
Model Number: Always Right 140 F to 260 F
Date Received in Plant: 3/2/95

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Slide 40

Teaching points:

Review examples of records p. 122



Slide 41

Teaching points:

Review examples of records p. 123

Slide 42

Teaching points:

Review examples of records p. 124

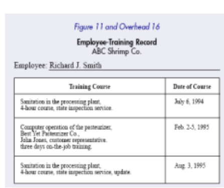


Figure 11 and Overhead 16

Employee-Training Record
ABC Shrimp Co.

Employee: Richard J. Smith

Training Course	Date of Course
Sanitation in the processing plant, 4-hour course, state inspection service.	July 6, 1994
Computer operation of the pasteurizer, Best Yet Pasteurizer Co., John Jones, customer representative. three days on-the-job training.	Feb. 2-5, 1995
Sanitation in the processing plant, 4-hour course, state inspection service, update.	Aug. 3, 1995

Slide 43

Teaching points:

Review examples of records p. 108

Slide 44

Teaching points:

Review examples of records p. 109

Slide 45

Teaching points:

Review examples of records p. 125

Slide 46

Teaching points:

Review examples of records p. 126

Slide 47

Summary

- **There are 4 categories of records required in a HACCP operation:**
  - **HACCP plan and support documentation (includes sanitation monitoring and sanitation correction records)**
  - **CCP monitoring records**
  - **Corrective action records**
  - **Verification records**

Slide 48

Summary

- **Students should be able to identify:**
  - **the required information in the different categories of HACCP records**
  - **what should be documented**
  - **when records need to be reviewed**
  - **how to conduct a record review**
  - **how long records should be kept**

Slide 1

Chapter 12:
The Seafood HACCP Regulation

HACCP
Hazard Analysis Critical Control Point
Training Curriculum

Slide 2

History:

- Have students turn to Appendix 1 in the manual and show them the full context of the regulation.
- Give a brief history of the regulation
- Provide (if possible) and refer them to the preamble in the Federal Register and explain that the regulation was a joint effort between government and industry
- Discuss the objectives of the course as outlined in the manual

Objective: (overhead 1)
In this module, you will learn:
What are the requirements of the seafood HACCP regulation
How to reference the specific requirements

Slide 3

Regulation Format

- Explain the regulation format as having three main parts:
  - Subpart A: The general provisions that apply to all processors
  - Subpart B: Additional provisions that apply only to smoked and smoked flavor fish
  - Subpart C: Additional provisions that apply only to raw molluscan shellfish

Regulation Format (overhead 2)
- Subpart A - General provisions
- Subpart B - Smoked and smoke-flavored fishery products
- Subpart C - Raw molluscan shellfish

Slide 4

Chapter 12: The Seafood HACCP Regulation

Definitions 123.3

- Point out that all regulations define certain terms so there is consistency in the regulation.
- Explain some of the key definitions so that students will understand if and why their products would be covered by this regulation.
- Definitions of paramount importance are:
  - Fish and Fishery Product
  - Processor and Processing
  - Importer

Definitions (§123.3) (overhead 3)
Fish processing Importer
Fishery product processor

Slide 5

Chapter 12: The Seafood HACCP Regulation

Who must comply

- **Importer**
  - Holding importers responsible for product that they bring into the US was FDA's attempt at a level playing field for all processors, domestic and foreign
  - FDA is capable of inspecting only about 250 foreign food firms per year so importers play a major role in determining compliance with foreign processors
- **Processor – domestic and foreign**
  - Together the terms importer, processor and processing define who is subject to the regulation

Who must comply (Overhead 4)

Slide 6

Chapter 12: The Seafood HACCP Regulation

This regulation does not apply to:

- **Harvest or Transport**
  - Harvest – explain that even though harvesters are exempt from the regulation, it does not exclude processors from control of hazards, such as histamine, at receipt.
  - Transport – explain that even though transporters are exempt from the regulation, it does not exclude processors from controls of hazards such as histamine or pathogen growth at receipt.

This regulation does not apply to: (overhead 5)
- The harvest or transport of fish or fishery products

Slide 7

Chapter 12: The Seafood HACCP Regulation

This regulation does not apply to: (cont)

- **Certain practices such as heading etc.**
  - Explain that only practices intended to hold the fish are excluded from the regulation
- **Retail**
  - Explain that even though retail is exempt from federal regulations that most states have adopted a HACCP regulation that retail establishments must comply with

This regulation does not apply to: (overhead 5)
- Practices such as heading, eviscerating or freezing intended solely to prepare a fish for holding on a harvest vessel
- The operation of a retail establishment

Slide 8

Chapter 12: The Seafood HACCP Regulation

Current Good Manufacturing Practices 123.5

- Discuss how the CGMP's fit with the requirements of the Seafood HACCP regulation
  - Explain that the CGMP's still apply to seafood processors and are the basis for determining whether the facilities, methods, practices and controls used are safe and if the products are produced under sanitary conditions.
  - The Seafood HACCP regulation took major sections of the CGMP's that were specific to seafood safety and made monitoring mandatory

Current Good Manufacturing Practices: (overhead 6)
- Regulations found in Title 21, Part 110 of the CFR's
- Proper practices for the safe and sanitary handling of all foods

Slide 9

Chapter 12: The Seafood HACCP Regulation

Hazard Analysis 123.6(a)

- Every processors shall have or have conducted a hazard analysis
  - It does not need to be written, however, a written HA may be useful to have for annual review and if there are disagreements with regulatory authorities about what hazard are or are not reasonably likely to occur.
  - FDA uses the firm's HACCP plan to determine if the firm has identified the appropriate hazards.

Hazard Analysis §123.6(a) (overhead 7)
- Every processor shall conduct or have conducted a hazard analysis

Slide 10

Chapter 12: The Seafood HACCP Regulation

Hazards that are "reasonably likely to occur"

- **"reasonably likely to occur"**
  - **In addition to the standard questions relating to experience, illness data etc., during the HA, one of the best questions to ask is "will this hazard occur in the absence of controls?"**
    - **Example: If the product is shrimp with sulfites:**
      - » **Some people would say that as long as it is labeled as containing sulfites the hazard is not reasonably likely to occur – that would be wrong because:**
      - » **If the firm did not label the shrimp as containing sulfites (in the absence of control), then the hazard would be reasonably likely to occur.**

Hazards that are reasonably likely to occur (overhead 8)

- **Hazards that are "reasonably likely to occur" are those "for which a prudent processor would establish controls"**

Slide 11

Chapter 12: The Seafood HACCP Regulation

HACCP Plan 123.6(b)

- **The HACCP plan is a "shall" requirement**
  - **If a processor does not have a HACCP plan when one is needed, FDA may take regulatory action**
- **The plan is specific to each specie of fish and fishery product**
  - **If the hazards and controls are the same they can be grouped under one Plan**

HACCP Plan §123.6(b) (Overhead 9)

- **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**

A HACCP plan shall be specific to: (Overhead 10)

- **Each species of fish and type of fishery product**
- **Each processing location**

Slide 12

Chapter 12: The Seafood HACCP Regulation

The **HACCP** plan shall:

- **Relate each one of the HACCP plan requirements to seven principles of HACCP discussed in previous chapters**
- **Point out that a pre-determined corrective action plan is not needed, and will be discussed under the corrective action section of the regulation**

The HACCP plan shall: (overhead 11)

Slide 13

The **HACCP** plan shall be signed and dated:

- **By the most responsible person or higher level official – because understanding and support of the Plan should start from the top**
- **Once signed, the HACCP plan is accepted and must be implemented**
- **In addition to the initial acceptance, the plan MUST be signed and dated upon any modification or at least annually.**

The HACCP plan shall be signed and dated by: (overhead 12)
The HACCP plan shall be signed and dated: (overhead 13)

Slide 14

Relationship of the Seafood HACCP regulation to:

- **Low Acid Canned Foods and Acidified Foods 123.6(e)**
  - **If a processor is producing an acidified or LACF they do not need to address the hazard of *C. botulinum* (only) in their HACCP plan but MUST address other hazards.**
    - Example: Histamine in canned tuna must be addressed in the HACCP plan, but the controls for *Clostridium botulinum* would not need to be.

No overhead

Slide 15

Relationship of Sanitation Controls and the HACCP Plan:

- **FDA recognizes that some hazards are controlled by sanitation and that including the controls in the HACCP plan are difficult at best**
- **Explain that if a processor is controlling a hazard such as cross contamination of a RTE product through sanitation controls that are not part of their Plan, their sanitation program must be strong enough to provide adequate controls. It might mean that sanitation monitoring would take place more often than if there was not a hazard being controlled by sanitation practices.**

No overhead

Slide 16

Chapter 12: The Seafood HACCP Regulation

Legal Basis 123.6(g)

- **Explain that this regulation was based primarily on section 402(a)(4) of the Food Drug and Cosmetic Act that states:**
  - **A food shall be deemed adulterated – if it has been prepared, packed , or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may be been rendered injurious to health**
  - **This means that if you do not comply with the regulation (including having a HACCP plan to control a hazard that is reasonably likely to occur) the product (whether domestic or import) can be considered adulterated and subject to regulatory action.**

No overhead

Slide 17

Chapter 12: The Seafood HACCP Regulation

Corrective Action 123.7

- **Whether pre-determined or not, the requirements for what a processor needs to do when taking a corrective action is best explained by saying:**
  - **Every corrective action must have two parts:**
    - **That no product that is either adulterated or injurious to health enters commerce**

    AND
    - **That the cause of the deviation is corrected**
- **If the corrective action plan is NOT included in your HACCP plan, you still need to take action on both the product and the process but in addition you will have to re-evaluate your HACCP plan to see if modifications are necessary to reduce the risk of further deviations.**

Corrective Action §123.7 (overhead 14)
Corrective Actions - Two Choices (overhead 15)
+ Alternate Procedure Predetermined

Slide 18

Chapter 12: The Seafood HACCP Regulation

Verification 123.8

- **HACCP Plan**
  - **Reassess once a year or whenever changes occur**
  - **Remember that it has to be reassessed by an individual that meets the training requirements.**
- **Hazard Analysis**
  - **If the firm does not have a HACCP plan, the hazard analysis must be reassessed when changes are made that could affect the analysis**

Verification §123.8 (overhead 16)
Every processor shall verify:
–That the HACCP plan is adequate to control the food safety hazards that are reasonably likely to occur
–That the HACCP plan is implemented effectively

Slide 19

Chapter 12: The Seafood HACCP Regulation

Ongoing verification: (Must be listed in HACCP Plan)

- **Consumer complaints**
  - **The processor needs to review to determine if they relate to a problem at a CCP – BUT – regulators do not have access to them.**
- **Calibration**
  - **Give examples of process monitoring instruments, thermometers, recorders, thermocouples. Verification should also list the frequency of calibration**
- **In or end product testing**
  - **If you choose to do in or end product testing and list it in your HACCP plan, regulators will have access to the records**

Ongoing verification (overhead 17)

Slide 20

Chapter 12: The Seafood HACCP Regulation

Review of Records – as part of verification

- **Record review must be listed as a verification procedure in your HACCP plan.**
  - **Suggest listing review of the required records at each CCP**
- **The records must be reviewed by someone who meets the training requirements**

Review of Records (overhead 18)
- CCP monitoring records
- Corrective-action records
- Calibration records
- In-process and end-product testing records

Slide 21

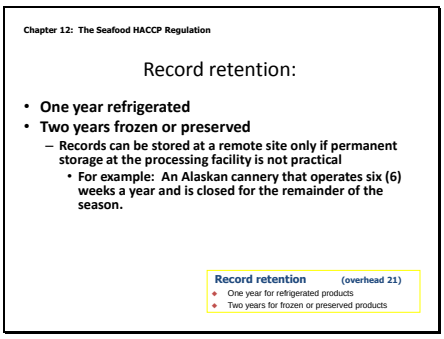
Chapter 12: The Seafood HACCP Regulation

Records required by the regulation:

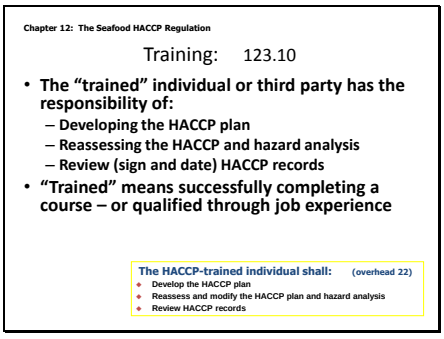
- **The records explain themselves by title, but it is important that students are told that they also have requirements:**
  - **Name and location of the processor – unless it is the processors only location**
  - **Date and time of the activity – that means they need to be completed when the activity occurs, not before, and not after**
  - **Be signed or initialed by the person making the record**
  - **Identify the product (and code if appropriate)**
  - **Be available for review**

Records required by the regulation (overhead 19)
Required information on each record (overhead 20)

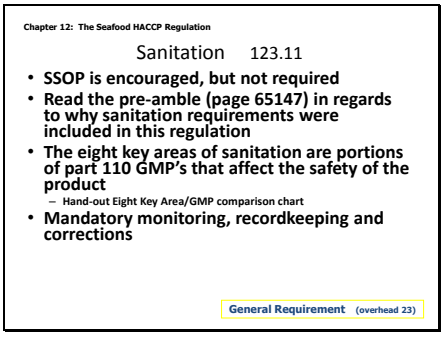
Slide 22



Slide 23



Slide 24



Slide 25

Chapter 12: The Seafood HACCP Regulation

Eight key sanitation conditions and practices:

- **Have available the Seafood HACCP Alliance Sanitation Control Course manual and suggest to attendees that they at least read the manual**
- **OR, if the manual is not available, have a copy of Module 7 of the Seafood HACCP Alliance Encore course which describes what is covered under the eight (8) key areas of sanitation and the expected frequency of monitoring**

Eight key sanitation conditions and practices: **(overhead 24)**

Slide 26

Chapter 12: The Seafood HACCP Regulation

Eight key sanitation conditions and practices (cont):

- **Remember that sanitation monitoring is required even if there is no need for a HACCP plan**
- **Implementation of sanitation monitoring is as important as implementation of the HACCP plan – especially in the production of ready-to-eat products where sanitation is being used to control a hazard**

Eight key sanitation conditions and practices: **(overhead 24)**

Slide 27

Chapter 12: The Seafood HACCP Regulation

Imported Products 123.12

- **The requirements for imported products were included in the regulation in an attempt to make a level playing field for both domestic and foreign processors**
- **FDA does not now, and probably will not any time soon, have an MOU with a foreign country**

Importer Verification: **(overhead 25)**

- **Import from countries with a memorandum of understanding (MOU)**
  OR
- **Implement verification procedures**

Slide 28

Chapter 12: The Seafood HACCP Regulation

Importer Verification Procedures

- **The easiest way to explain Importer requirements is to say that importers need to have three (3) things:**
  - **Written a verification procedures**
    - **Hand out or draw an example of a written verification procedure**
  - **Product specifications**
    - **Hand out an example of product specifications**
  - **Implemented an affirmative step**
    - **Describe the affirmative steps listed in the regulation**

Importer Verification Procedures: (overhead 25, 26, 27)
- Product specifications and
- Affirmative step
  - Affirmative steps may include any of the following……

Slide 29

Chapter 12: The Seafood HACCP Regulation

Smoked and Smoke-Flavored Fishery Products 123.15 and 123.16

- **The HACCP plan for these products must include controls for *Clostridium botulinum* because these products have been linked to cases of botulinum**
  - **Remind students that if other significant hazards such as pathogen growth are also identified they must also be included in the plan**

Smoke and Smoke-Flavored Fishery Products: (overhead 28)
- HACCP plan must include controls for *Clostridium botulinum* toxin formation for the shelf life of the product under normal and moderate abuse conditions
- Where product is subject to 21 CFR 113 or 114, the HACCP plan need not include such controls

Slide 30

Chapter 12: The Seafood HACCP Regulation

Raw Molluscan Shellfish 123.20 and 123.28

- **It is important to know that the largest reported illnesses from consumption of seafood is caused by raw molluscan shellfish. This portion of the regulation sets out specific requirements for raw molluscan shellfish**
- **Even though the molluscan shellfish industry is subject to significant regulatory oversight in those states that participate in those programs (such as the NSSP) there are states that don't participate and have little oversight.**

Raw Molluscan Shellfish 123.20: (overhead 29)
- HACCP plans must include a means for controlling the origin of the raw molluscan shellfish
- Where processing includes a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern, the HACCP plan need not include controls on sources of origin

Slide 31

Chapter 12: The Seafood HACCP Regulation

Raw Molluscan Shellfish 123.28

Control of Communicable Diseases 1240.60

- This portion of the regulation sets out specific requirements for raw molluscan shellfish
- Most of the requirements are source controls because the risk of the hazard is reduced by harvesting molluscan shellfish from sanitary growing waters
- The source controls include license, receiving record, labeling and tag requirements

Raw Molluscan Shellfish: (overhead 30, 31, 32, 33,34, and 35)

- Processors shall only process molluscan shellfish from....
- Shellstock receiving.....
- Required information on tags.....
- Records for shellstock receiving must document....
- Shucked molluscan shellfish containers must bear a label that contains.....
- Records for shucked product must document.....

Slide 1

Chapter 13: Sources of Information on Preparing HACCP Plans

Slide 2

Learning Objectives:

- **What sources of information exist to help you identify seafood safety hazards and establish control measures**
- **How to use the Fish and Fishery Products Hazards and Controls Guidance to identify hazards and establish control measures**

2

Slide 3

Visual Aids:

- **Blank hazard analysis and HACCP plan forms and overheads or LCD projection**
- **Forms keyed to Hazards Guide**
- **Fish and Fishery Products Hazards and Control Guidance (Hazards Guide)**
- **HACCP course training curriculum**
- **Examples of HACCP references**
- **Post-its (optional)**

3

Slide 4

Key Sources of Information

- Personnel
- Publications
- Internet Sources
- References

4

Slide 5

Personnel p. 146

- Seafood processor
- Trade associations
- Consultants and auditors
- University Sea Grant/Cooperative Extension
- Government seafood inspectors
- Suppliers, buyers and analytical labs

5

Slide 6

Publications p. 147-149

- HACCP Manual
- Fish and Fishery Product Hazards and Controls Guidance
- Compliance Policy Guides
- Import Alerts
- National Shellfish Sanitation Program manuals
- USDA
- Model Seafood Surveillance Project (NMFS)*
- Seafood Safety (NAS)*
- Morbidity and Mortality Weekly Report (CDC)
- Recommended International Code of Practice (CODEX)

*** out of date**

6

Slide 7

Internet Sources p. 149 -150

- FDA's Home Page
- Regulatory Fish Encyclopedia
- AquaNIC
- USDA (now – FoodSafety.gov)
- Seafood Discussion Group
- SeafoodNIC
- Compendium of Fish and Fishery Processes, Hazards and Controls

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Slide 8

Seafood Discussion Group (Mailing List)
p. 150

To: listproc@ucdavis.edu
Subject: [leave the subject blank]
Message: subscribe seafood [first name] [last name]
--

Must be in plain text; not html code.
Type two dashes (--) on the line after subscribing "seafood" and your name.

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Slide 9

Seafood Discussion Group (Mailing List)
p. 150

http://seafood.ucdavis.edu/listserv/listserv.htm

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Slide 10

Seafood Discussion Group (Mailing List)

Subscription alternative:

- **Send a request to: pdtom@ucdavis.edu**
- **Mention seafood HACCP list**
- **Include:**
  - **first and last name**
  - **e-mail address**

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Slide 11

Compendium of Fish and Fishery Product Processes Hazards and Control p. 150

11

Slide 12

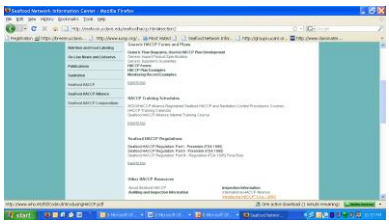
Compendium – General Outline

- **Potential Food Safety Hazards**
- **Control Measures**
- **Guidelines (Federal, State)**
- **Process Establishment**
- **Critical Aspects of Process**
- **Growth**
- **Heat Resistance**
- **Analytical Procedures**
- **HACCP Plan Examples**
- **Commercial Test Products**
- **Processes**
- **Time Temperature Monitoring Tags**
- **References**

12

Slide 13

Generic HACCP Forms and Plans



13

Slide 14

HACCP Training Calendar

14

Slide 15

Key Parts of the Curriculum 1:2

- **p. 35 Processing narrative**
- **p. 38 Flow diagram**
- **p. 39-49 Model SSOP**
- **p. 68-72 Hazard Analysis**
- **p. 125-26 HACCP Plan**
- **p. 151-153 How to use the Guide**

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Slide 16

Key Parts of the Curriculum 2:2

- Appx 1 – FDA Seafood HACCP rule
- Appx 2 – HACCP worksheets
- Appx 3 – Hazards found in seafood
- Appx 4 – CCP decision tree
- Appx 5 – 8 models
- Appx 6 – Current GMPs

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Slide 17

How to Use the Hazards Guide

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Slide 18

Key Parts of the Hazards Guide

- Ch. 1 Introduction (changes)
- Ch. 2 Steps 1-13 (18 total)
- Ch. 3 Potential hazards tables (3)
- Ch. 4-21 Hazards and steps 10-18 plus control strategies and plans

18

Slide 19

8 Appendices

1. Forms (HA and HACCP)
2. Sample Product Flow Diagram
3. CCP Decision Tree (helps identify CCP)
4. Bacterial Pathogen Growth and Inactivation
5. FDA & EPA Safety Levels in Regulations and Guidance
6. Food Allergens (includes fish and crustacean shellfish)
7. Bibliography
8. Seafood HACCP Regulation

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Slide 20

Using chapter 2, p. 11

- Use the HA and HACCP forms
- Follow steps 1-13 in chapter two
- Select one of the 4-21 chapters in the Guide to walk the participants up to step 18
- Show how the steps in the book correspond to the columns on the forms

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Slide 21

Slide 22

Hazard Analysis Worksheet

Guide p. 12; Curriculum p. 68-72

HA Form

- **Step 6: Record each of the processing steps from the flow diagram in column 1 of HA form**
- **Step 7: Identify potential species-related hazards (p. 43) in column 2**
- **Step 8: Identify potential process-related hazards (p. 45) in column 2**

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Slide 23

Hazard Analysis Worksheet

Guide p. 12; Curriculum p. 68-72

HA Form

- **Step 9: Complete the HA worksheet by consulting chapters 4-21**
- **Step 10: understand the potential hazard**
- **Step 11: determine if the potential hazard is significant**
- **Step 12: identify the critical control points**
- **Complete steps 10-12 in the chapters relating to each of the potential hazards**

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Slide 24

How to Use the Hazards Guide

p. 152

- **Step 13: Complete the HACCP Plan Form**
- **Step 14: Set the critical limits**
- **Step 15: Establish monitoring procedures: What, How, Frequency, and Who**
- **Step 16: Establish corrective action procedures**
- **Step 17: Establish a record-keeping system**
- **Step 18: Establish verification procedures**

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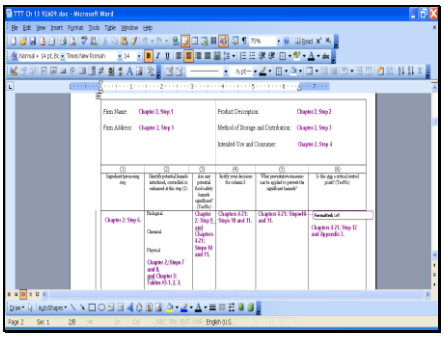
Slide 25

Further practice:

- Use the shrimp example from the text and review the 18 steps to show how to use the Guide in developing a HA worksheet and HACCP plan.
- Encourage students to look at chapters in the Guide, review the HACCP plan examples, and try to determine how the plan was developed.
- Students can ask questions on day 3 of the course.

25

Slide 26



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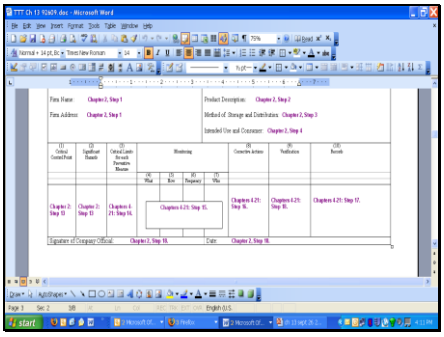


Slide 1

The Seafood HACCP Alliance Internet Course

An Alternative Training Format
Managed by:
New York Sea Grant and
Cornell University

Slide 2

Course Structure

Segment One
Self Study on the Internet
Replaces Days 1 and 2 of the "live" 3-day Alliance course

Segment Two
1 Day Session with Instructor
Similar to Day 3 of "live" 3-day Alliance course

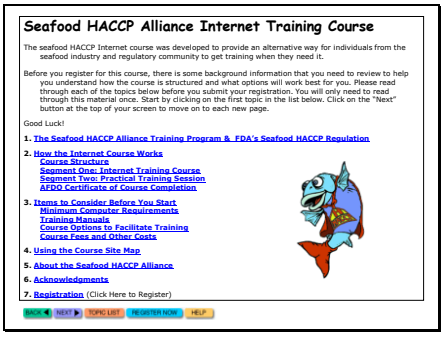
Segment One Only - Students get Completion Notice from Cornell

Segment One + Two - Students are eligible for AFDO Certificate

Slide 3

http://seafoodhaccp.cornell.edu

Slide 4



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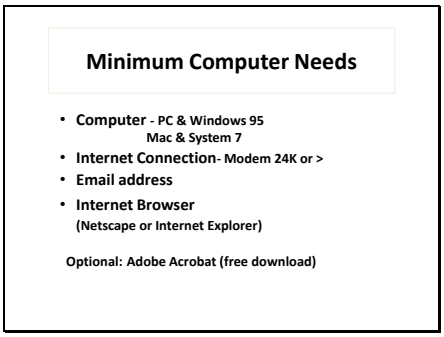

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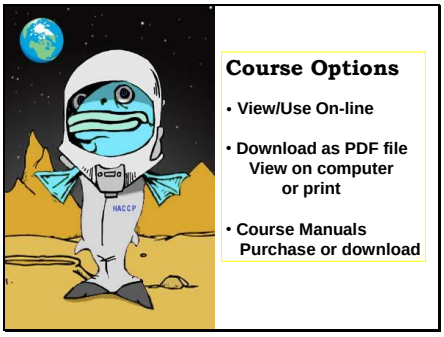
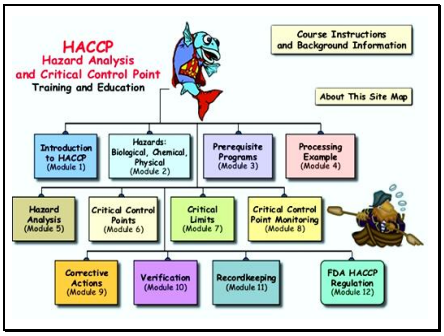


Slide 7

How the Course Works

- **Registration – via Internet or by Mail**
  $50 fee + manuals (if needed)
  Password & Username- Create Cornell Guest ID
  (Necessary to get access to course modules)
- **Student tracking - by each unique Username**
- **Module completion - Submit "Check Your Knowledge" answers via Internet**
- **Self Paced Individual Learning - Complete Modules within 6 months** 12

Slide 8



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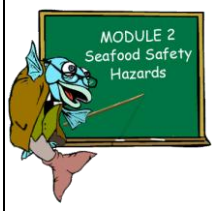
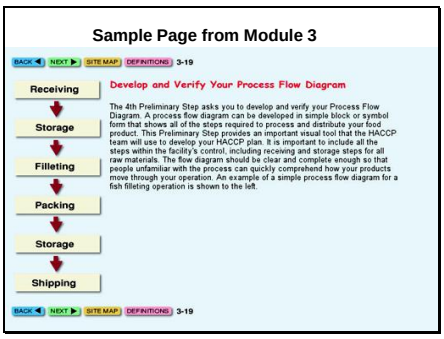


Module Format

- **Introduction**
- **Review Text & Examples (emphasis on "How To")**
- **Links for more Info**
- **Interactive Worksheets**
- **Check Your Knowledge**
- **Student Tracking**

Slide 10



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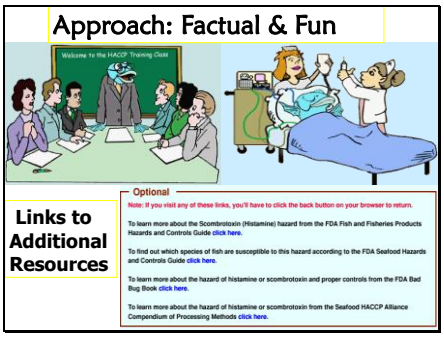

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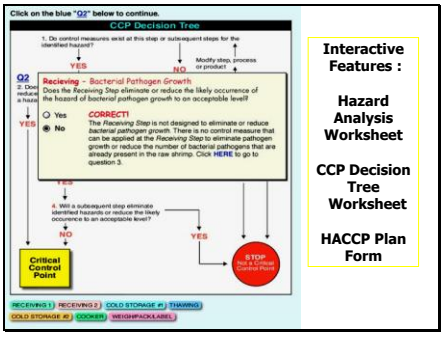

Slide 13

Answers to review questions submitted online for each module.

Automatic tracking of student progress

Steve Michael Kern — 3GP1Y2: Seafood HACCP Alliance Training Program

Module 1: Check Your Knowledge

Instructions:
Enter your answers from the Check Your Knowledge Form.

Question 1 (5 points)
The first time that the HACCP concept was applied to food production in the U.S. was when the FDA Seafood HACCP regulation was implemented in 1997

O TRUE
O FALSE

Question 2 (5 points)
Which of the following is not one of the seven principles of HACCP:

O Establish critical limits
O Conduct a hazard analysis
O Clean and sanitize your plant
O Establish record keeping procedures

Question 3 (5 points)
Once a HACCP plan has been created, it cannot be changed to utilize new control procedures or monitoring techniques that are developed.

O TRUE
O FALSE

Slide 14

Step 1 - Go to http://seafoodhaccp.cornell.edu and review course structure and requirements

Step 2 - Register online or by regular mail and pay $50 registration fee

Step 3 - Look for Email with instructions on how to create a Cornell Guest ID and create & activate a unique Username & Password

Step 4 – Receive Email verification of Guest ID completion and URL of active course site

Step 5 – Work on 12 Course Modules and complete within 6 months of registration date

Step 6 – Receive Email letter from Cornell showing that Segment One Internet course is completed

Step 7 - Register for Segment Two session if AFDO Certificate is needed

Slide 15

Internet Course Participation

October 2001 to April 2006

2,050 Students have enrolled in the course

76% from industry; 18% from regulatory agencies

Students from 49 U. S. States & 30 Countries

1. NY - 291
2. FL - 163
3. CA - 145
4. ME - 113
5. OH - 96
6. NJ - 88
7. MD - 73
8. TX - 67
9. MA - 60
10. IL & MN - 53 each

Canada, Australia, N.Zealand, Japan, China, Korea, Singapore, Vietnam, Taiwan, Mexico, Honduras, Venezuela, Panama, Guyana, Trinidad, Bahamas, Dominican Republic, Ecuador, Peru, South Africa, Mozambique, Namibia, Mauritius, Kuwait, UAE, Jordan, Spain, France, Greece, Denmark

Major organizations = FDA, State Regulatory Agencies, Wal-Mart; Restaurant Depot; Blount Seafood; Icelandic, Safeway

Slide 16

Internet Course Feedback

- **Majority of students use: PC, Internet Explorer, and a 56K phone modem or cable connection**
- **Mean Rating of 4.55 (n=1,297) On 5 point scale where 5 = Excellent and 1 = Poor**
- **Total Time to Complete Internet Course - Mean = 12.7 Hours; Median & Mode = 10 Hours**
- **Most Modules take 40-45 minutes Module 5 - 90 minutes, Modules 2 & 12 - 60 min.**

Slide 17

Segment Two
One Day "Live" Course

- **Students must complete the Internet course first**
- **Proof of Internet course completion + attending a registered Segment Two course makes students eligible to receive the same Association of Food & Drug Officials "Certificate of Course Completion" provided upon completion of a "live" three day Alliance course.**
- **Segment Two courses need prior AFDO approval & a "trained" instructor must conduct the course.**

Slide 18

Teaching the Segment Two
1-Day "Live" Training Course

Step 1 – Submit course application to AFDO

Step 2 – Advertise course & accept registrations

Step 3 – Teach course using AFDO/Alliance Protocol

Step 4 – Submit student registration forms, proof of Internet Course completion, and appropriate fees to AFDO for processing of certificates

Step 5 – Students receive AFDO "Certificate of Course Completion"

Slide 19

Teaching points:

- Start with Introductions & Overview
- Schedule at least 1-2 hours to review:
  - Sanitation/Prerequisite programs,
  - HACCP Principles & FDA regulation
  - FDA Hazards and Controls Guide
  - HACCP Plan Development Process & Forms
- Select Model(s) for HACCP Plan Team Activity
- Provide guidance for each team as they work through the Hazard Analysis & HACCP Plan
- Review Results & Answer Questions

See Sample Course Agenda in AFDO/Alliance Protocol

Slide 20

Learning Objectives:

- Brief review of HACCP Principles and the FDA Seafood HACCP Regulation
- Tools for writing the HACCP Plan:
  - Forms (Hazard Analysis & HACCP Plan)
  - FDA Hazards and Controls Guide
  - Sources of information and help
- Team work sessions to write a HACCP Plan using Alliance Models
- Presentation and discussion of team results

Slide 21

Materials and aids:

For Instructors

- AFDO Student Information Sheet Form for each student
- Course Agenda
- Supplemental handout materials
- Alliance Manual (Blue Book) & FDA Hazards Guide (Purple Book)

Slide 22

Materials and aids:

- Selected overheads from Chapters 1-12 to briefly review HACCP principles; FDA regulation; & the Hazard Analysis Worksheet and HACCP Plan Form *PowerPoint slides available from Lori Pivarnik of the University of Rhode Island pivarnik@uri.edu*
- Copies of different Models from Appendix 5 of Alliance Training manual with blank copies of Haz. Analysis & HACCP Plan forms for each student
- Blank Hazard Analysis & HACCP Plan Forms on overhead transparencies (and transparency pens) for students to present team results

Slide 23

Materials and aids:

For Students

- Must bring Email with subject "Course Completion Notice" from Cornell Univ. & Seafood HACCP Alliance showing that Internet course has been completed
- Copy of the FDA Fish & Fishery Products Hazards and Controls Guide
- Students must also fill out AFDO/Alliance Student Information Sheet provided with course approval.

Slide 24

Summary

- The Internet + Segment Two format is flexible and effective
- First phase of training is available on demand
- Accommodates individual needs and learning styles