

## The HACCP Plan Form

This guidance is designed to walk you through a series of eighteen steps that will yield a completed HACCP plan. A blank HACCP Plan Form is contained in Appendix 1. Note that this is a two page form, with the second page to be used if your process has more critical control points than can be listed on one page. The Seafood HACCP Regulation requires that you prepare a HACCP plan for fish and fishery products that you process (where significant safety hazards exist). The regulation does not require that you use the form included in Appendix 1. However, using this standardized form will likely help you develop an acceptable plan and will expedite regulatory review.

## The Hazard Analysis Worksheet

In order to Complete the HACCP Plan Form you will need to perform a process called “hazard analysis.” FDA has found that the use of a standardized Hazard Analysis Worksheet assists in this process. A blank Hazard Analysis Worksheet is contained in Appendix 1. Note that this is also a two page form, with the second page to be used if your process has more processing steps than can be listed on one page. While the Seafood HACCP Regulation requires that processors perform a hazard analysis, it does not require that it be kept in writing. However, FDA expects that a written hazard analysis will be very useful when you perform mandatory HACCP plan reassessments, and when you are asked by regulators to justify why certain hazards were or were not included in your HACCP plan.

## The Steps

Following is a listing of the steps that this guidance uses in HACCP plan development:

- Preliminary Steps
  - General information
  - Describe the food
  - Describe the method of distribution and storage
  - Identify the intended use and consumer
  - Develop a flow diagram
- Hazard Analysis Worksheet
  - Set up the Hazard Analysis Worksheet
  - Identify the potential species-related hazards
  - Identify the potential process-related hazards
  - Complete the Hazard Analysis Worksheet
  - Understand the potential hazard
  - Determine if the potential hazard is significant
  - Identify the critical control points (CCP)
- HACCP Plan Form
  - Complete the HACCP Plan Form
  - Set the critical limits (CL)
  - Establish monitoring procedures
    - What
    - How
    - Frequency
    - Who
  - Establish corrective action procedures
  - Establish a recordkeeping system
  - Establish verification procedures

## Preliminary Steps

### STEP #1: GENERAL INFORMATION.

Record the name and address of your processing facility in the spaces provided on the first page of the Hazard Analysis Worksheet and the HACCP Plan Form (Appendix 1).

### STEP #2: DESCRIBE THE FOOD.

Identify the market name or Latin name (species) of the fishery component(s) of the product.

*Examples:*

- *tuna*
- *shrimp*
- *jack mackerel*

Fully describe the finished product food.

*Examples:*

- *individually quick frozen, cooked, peeled shrimp*
- *fresh tuna steaks*
- *frozen, surimi-based, imitation king crab legs*
- *fresh, raw drum, in-the-round*
- *raw shrimp, in-shell*
- *raw, shucked soft clams*
- *fresh seafood salad, with shrimp and blue crab meat*
- *frozen, breaded pollock sticks*
- *frozen lobster cakes*

Describe the packaging type.

*Examples:*

- *vacuum-packaged plastic bag*
- *aluminum can*
- *bulk, in wax-coated paperboard box*
- *plastic container with snap lid*

Record this information in the space provided on the first page of the Hazard Analysis Worksheet and the HACCP Plan Form.

### STEP #3: DESCRIBE THE METHOD OF DISTRIBUTION AND STORAGE.

Identify how the product is distributed and stored after distribution (e.g. frozen, refrigerated, on ice, or dry). Identify whether any special shipping methods, such as mail order, are used.

*Examples:*

- *stored and distributed frozen*
- *distributed on ice and then stored under refrigeration or on ice*
- *distributed through mail order with chemical refrigerant and then stored under refrigeration*

Record this information in the space provided on the first page of the Hazard Analysis Worksheet and the HACCP Plan Form.

### STEP #4: IDENTIFY THE INTENDED USE AND CONSUMER.

IDENTIFY HOW THE product will be used by the end user or consumer.

*Examples:*

- *to be heated (but not fully cooked) and served*
- *to be eaten with or without further cooking*
- *to be eaten raw or lightly cooked*
- *to be fully cooked before consumption*
- *to be further processed into a heat and serve product*

Identify the intended consumer or user of the product. The intended consumer may be the general public or a particular segment of the population, such as infants or the elderly. The intended user may be another processor, who will further process the product.

*Examples:*

- *by the general public*
- *by the general public, including some distribution to hospitals and nursing homes*
- *by another processing facility*

Record this information in the space provided on the first page of the Hazard Analysis Worksheet and the HACCP Plan Form.

## **STEP #5: DEVELOP A FLOW DIAGRAM.**

The purpose of the diagram is to provide a clear, simple description of the steps involved in the processing of your fishery product and its associated ingredients as they “flow” from receipt to distribution. The flow diagram should cover all of the steps in the process which your firm performs. Receiving and storage steps for each of the ingredients, including non-fishery ingredients, should be included. The flow diagram should be verified on-site for accuracy.

Figure # A-1 (Appendix 2) is an example of a flow diagram.

## **Hazard Analysis Worksheet**

### **STEP #6: SET UP THE HAZARD ANALYSIS WORKSHEET.**

Record each of the processing steps (from the flow diagram) in Column 1 of the Hazard Analysis Worksheet.

### **STEP #7: IDENTIFY THE POTENTIAL SPECIES-RELATED HAZARDS.**

Find in Table #3-1 (Chapter 3) or Table #3-2 (Chapter 3) the market name (Column 1) or Latin name (Column 2) of the product that you identified in Step #2. Use Table #3-1 for vertebrates (animals with backbones), such as finfish. Use Table #3-2 for invertebrates (animals without backbones), such as shrimp, oysters, crab, and lobster. Determine if it has a potential species related hazard by looking for a “✓” mark (or three letter code for a natural toxin) in the right-hand columns of the table. If so, record the potential hazard(s) in Column 2 of the Hazard Analysis Worksheet, at each processing step.

Tables #3-1 and 3-2 include the best information currently available to FDA concerning hazards that are specific to each species of fish. You should use your own expertise, or that of outside experts, as necessary, to identify any hazards that may not be included in the table (e.g. those that may be new or unique to your region).

You may already have effective controls in place for a number of these hazards as part of your routine or traditional handling practices. The presence of such controls does not mean that the hazard is not significant. The likelihood of a hazard should be judged in the absence of controls. For example, the fact that histamine development in a particular species of fish has not been noted, may be the result of: 1) the inability of the fish to produce histamine; or 2) the existence of controls that are already in place to prevent its development (e.g. harvest vessel temperature controls). In the first case the hazard is not reasonably likely to occur. In the second case the controls should be included in the HACCP plan.

FDA plans to update Tables #3-1 and 3-2 as the agency becomes aware of new information.

### **STEP #8: IDENTIFY THE POTENTIAL PROCESS-RELATED HAZARDS.**

Find in Table #3-3 (Chapter 3) the finished product, package type, and method of distribution and storage that most closely matches the information that you developed in Steps #2 and 3. Record the potential hazard(s) listed in the table for that product into Column 2 of the Hazard Analysis Worksheet at each processing step.

You may need to include potential hazards for more than one finished product food category in Table #3-3. This will happen when your product fits more than one description. For example if you process shrimp salad using raw shrimp as a raw material, you are processing both a cooked product (i.e. the intermediate cooked shrimp) and a salad (i.e. the finished product shrimp salad). Potential hazards from both finished product food categories apply to your product and should be listed in Column 2 of the Hazard Analysis Worksheet.

Table #3-3 includes the best information currently available to FDA concerning hazards that are related to specific processing techniques. You should use your own expertise, or that of outside experts as necessary, to identify any hazards that may not be included in the table (e.g. those that are new or unique to your physical plant, equipment, or process). This is more likely with more complex or innovative products.

FDA plans to update Table #3-3 as the agency becomes aware of new information.

### **STEP #9: COMPLETE THE HAZARD ANALYSIS WORKSHEET.**

Consult the hazards and controls chapters of this guidance (Chapters 4 through 21) for each of the potential hazards that you entered in Column 2 of the Hazard Analysis Worksheet. These chapters offer guidance for completing your hazard analysis and developing your HACCP plan.

Complete Steps #10 through 12 in the chapters relating to each of the potential hazards. These steps involve: understanding the potential hazard; determining if the potential hazard is significant; and identifying the critical control points. When you have finished these steps for all of the potential hazards that relate to your product, you will have completed the Hazard Analysis Worksheet. You may then proceed to Step #13.

### **STEP #13: COMPLETE THE HACCP PLAN FORM.**

Find the processing steps which you have identified as CCPs in Column 6 of the Hazard Analysis Worksheet. Record the names of these processing steps in Column 1 of the HACCP Plan Form. Enter the hazard(s) for which these processing steps were identified as CCPs in Column 2 of the HACCP Plan Form. This information can be found in Column 2 of the Hazard Analysis Worksheet.

Complete the HACCP Plan Form by consulting the hazards and controls chapters of this guidance (Chapters 4 through 21) for each of the significant hazards that you entered in Column 2 of the HACCP Plan Form. Complete Steps #14-18 in the chapters relating to each of the significant hazards. These steps involve: setting the critical limits; establishing monitoring procedures; establishing corrective action procedures; establishing a recordkeeping system; and establishing verification procedures. When you have finished these steps for all of the significant hazards that relate to your product, you will have completed the HACCP Plan Form.

You should then sign and date the first page of the HACCP Plan Form. The signature must be that of the most responsible individual on-site at your processing facility or a higher level official. It signifies that the HACCP plan has been accepted for implementation by your firm.