# CHAPTER 2: **Conducting a Hazard Analysis and Developing a HACCP Plan**

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## THE HACCP PLAN FORM

This guidance document is designed to walk you through a series of 18 steps that will yield a completed Hazard Analysis Critical Control Point (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 Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products regulation, 21 CFR 123 (hereinafter, the Seafood HACCP Regulation), requires that you prepare a HACCP plan for fish and fishery products that you process if there are significant food safety hazards associated with the products. The regulation does not require that you use the form included in Appendix 1. However, using this standardized form may help you develop an acceptable plan and will expedite regulatory review. A separate HACCP plan should be developed for each location where fish and fishery products are processed and for each kind of fish and fishery product processed at that location. You may group products together in a single HACCP plan if the food safety hazards and controls are the same for all products in the group.

## THE HAZARD ANALYSIS WORKSHEET

In order to complete the HACCP Plan Form, you will need to perform a process called hazard analysis. The Seafood HACCP Regulation requires that all seafood processors conduct, or have conducted for them, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur in their product and to the preventive measures that a processor can apply to control those hazards (21 CFR 123.6(a)). FDA has found that the use of a standardized Hazard Analysis Worksheet assists with 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. The Seafood HACCP Regulation does not require that the hazard analysis be kept in writing. However, FDA expects that a written hazard analysis will be 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 list of the steps that this guidance uses in HACCP plan development:

- **Preliminary Steps**
  - Provide 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 potential species-related hazards;
  - Identify potential process-related hazards;
  - Understand the potential hazard;
  - Determine whether the potential hazard is significant;
  - Identify critical control points.
- **HACCP Plan Form**
  - Set up the HACCP Plan Form;
  - Set critical limits;
  - Establish monitoring procedures:
    - What,
    - How,
    - Frequency,
    - Who;
  - Establish corrective action procedures;
  - Establish a recordkeeping system;
  - Establish verification procedures.

## PRELIMINARY STEPS

### **STEP 1:** Provide general information.

Record the name and address of your processing facility in the spaces provided on the first page of both 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 (Thunnus albacares);*
- *Shrimp (Pandals spp.);*
- *Jack mackerel (Trachurus spp.).*

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 clams;*
- *Fresh seafood salad, with shrimp and blue crabmeat;*
- *Frozen, breaded pollock sticks;*
- *Frozen crab 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 both 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.

*Examples:*

- *Stored and distributed frozen;*
- *Distributed on ice and then stored under refrigeration or on ice.*

Record this information in the space provided on the first page of both 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 also be another processor that 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 both 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 steps in the process that 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.

Biological, chemical, and physical hazards can affect the safety of fishery products. Some food safety hazards are associated with the product (e.g., the species of fish, the way in which the fish is raised or caught, and the region of the world from which the fish originates). These hazards are introduced outside the processing plant environment before, during, or after harvest. This guidance refers to these as "species-related hazards." Other food safety hazards are associated with the way in which the product is processed (e.g., the type of packaging, the manufacturing steps, and the kind of storage). These hazards are introduced within the processing plant environment. This guidance refers to these as "process-related hazards." They are covered in Step 8.

Find in Table 3-2 (Chapter 3) or Table 3-3 (Chapter 3) the market name (Column 1) or

Latin name (Column 2) of the product that you identified in Step 2. Use Table 3-2 for vertebrates (animals with backbones) such as finfish. Use Table 3-3 for invertebrates (animals without backbones) such as shrimp, oysters, crabs, and lobsters. Determine whether the species has a potential species-related hazard by looking for a "√" mark (or one- or three-letter codes for a natural toxin) in the right-hand columns of the table. If it does, record the potential species-related hazard(s) in Column 2 of the Hazard Analysis Worksheet, at every processing step.

Tables 3-2 and 3-3 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 occurring should be judged in the absence of controls. For example, the fact that scombrotoxin (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 time and temperature controls). In the first case, the hazard is not reasonably likely to occur. In the second case, the hazard is reasonably likely to occur, and the controls should be included in the HACCP plan.

## **STEP 8:** Identify potential process-related hazards.

Find in Table 3-4 (Chapter 3) the finished product food (Column 1) and package type (Column 2) that most closely match the information that you developed in Steps 2 and 3. Record the potential hazard(s) listed in the table for that product in Column 2 of the Hazard Analysis Worksheet, at every processing step.

You may need to include potential hazards for more than one finished product food category from Table 3-4, which will happen when your product fits more than one description. For example, if you cook shrimp and use it to prepare a finished product salad, you should look at both the "cooked shrimp" and the "salads … prepared from ready-to-eat fishery products" categories in Table 3-4, Column 1. 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 3-4 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).

## **STEP 9:** Understand the potential hazard.

Consult the hazards and controls chapters of this guidance document (Chapters 4 through 7, 9, and 11 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. Each chapter contains a section, "Understand the Potential Hazard," that provides information about the significance of the hazard, the conditions under which it may develop in a fishery product, and methods available to control the hazard.

## **STEP 10:** Determine whether the potential hazard is significant.

Narrow the list of potential hazards that you entered in Column 2 of the Hazard Analysis Worksheet to those that are significant or, in other words, "reasonably likely to occur." The Seafood HACCP Regulation defines a food safety hazard that is reasonably likely to occur as "one for which a prudent processor would establish controls because experience, illness data,

scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls."

The hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Determine Whether this Potential Hazard Is Significant," that provides information about how to assess the significance of potential hazards. You should evaluate the significance of a potential hazard independently at each processing step. It may be significant at one step but not at another. A potential hazard is significant at the processing or handling step if (1) it is reasonably likely that the hazard can be introduced at an unsafe level at that processing step; or (2) it is reasonably likely that the hazard can increase to an unsafe level at that processing step; or (3) it is significant at another processing or handling step and it can be prevented, eliminated, or reduced to an acceptable level at the current processing or handling step. When evaluating the significance of a hazard at a processing step, you should consider the method of distribution and storage and the intended use and consumer of the product, which you developed in Steps 3 and 4.

If you determine that a potential hazard is significant at a processing step, you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If you determine that a potential hazard is not significant at a processing step, you should answer "No" in that column. You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps 11 through 18 for a hazard for those processing steps where you have recorded a "No."

It is important to note that identifying a hazard as significant at a processing step does not mean that it must be controlled at that processing step. Step 11 will help you determine where in the process the critical control point is located.

## **STEP 11:** Identify critical control points.

For each processing step where a significant hazard is identified in Column 3 of the Hazard Analysis Worksheet, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure A-2 (Appendix 3) is a critical control point (CCP) decision tree that can be used to aid you in your determination.

The hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Identify Critical Control Points (CCPs)," which provides information about where control should be exercised. Each chapter discusses one or more "control strategy example(s)" for how the hazard can be controlled, because there are often more ways than one to control a hazard. CCP(s) for one control strategy example often differ from those of another example for the same hazard. The control strategies contain preventive measure information. Record the preventive measure(s) in Column 5 of the Hazard Analysis Worksheet for each "Yes" answer in Column 3.

For every significant hazard, there must be at least one CCP where the hazard is controlled (21 CFR 123.6(c)(2)). In some cases, control may be necessary at more than one CCP for a single hazard. In other cases, a processing step may be a CCP for more than one hazard. CCPs are points in the process (i.e., processing steps) where the HACCP control activities will occur. Control activities at a CCP can effectively prevent, eliminate, or reduce the hazard to an acceptable level (21 CFR 123.3(b)).

If you determine that a processing step is a CCP for a significant hazard, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet. If you determine that a processing step is not a CCP for a significant hazard, you should enter "No" in that column. You need not complete Steps 12 through 18 for a hazard for those processing steps where you have recorded a "No."

## HACCP PLAN FORM

### **STEP 12:** Set up the HACCP Plan Form.

Find the processing steps that 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 Steps 13 through 18 for each of the significant hazards. These steps involve setting critical limits, establishing monitoring procedures, establishing corrective action procedures, establishing a recordkeeping system, and establishing verification procedures.

### **STEP 13:** Set critical limits.

For each processing step where a significant hazard is identified on the HACCP Plan Form, identify the maximum or minimum value to which a parameter of the process must be controlled in order to control the hazard. Each control strategy example provided in the hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Set Critical Limits," that provides information about appropriate critical limits for each of the control strategy example(s) discussed.

You should set a critical limit at such a value that if it is not met, the safety of the product may be questionable. If you set a more restrictive critical limit, you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a critical limit that is too loose, you could, as a result, allow an unsafe product to reach the consumer.

As a practical matter, it may also be advisable to set an operating limit that is more restrictive than the critical limit. In this way, you can adjust the process when the operating limit is not met, but before a critical limit deviation would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the critical limit.

Consider that the critical limit should directly relate to the parameter that you will be monitoring. For example, if you intend to monitor the temperature of the water in the cooker and the speed of the belt that carries the product through the cooker (because you have determined that these factors result in the desired internal product temperature for the desired time), you should specify water temperature and belt speed as critical limits, not the internal temperature of the product.

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

### **STEP 14:** Establish monitoring procedures.

For each processing step where a significant hazard is identified on the HACCP Plan Form, describe monitoring procedures that will ensure that critical limits are consistently met (21 CFR 123.6(c)(4)). The hazards and controls chapters of this guidance document (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Establish Monitoring Procedures," that provides information about appropriate monitoring procedures for each of the control strategy example(s) discussed.

To fully describe your monitoring program, you should answer four questions: (1) What will be monitored? (2) How will monitoring be done? (3) How often will monitoring be done (frequency)? and (4) Who will do the monitoring?

It is important for you to keep in mind that the monitoring process should directly measure the parameter for which you have established a critical limit. The necessary frequency of monitoring is dependent upon the circumstances. Continuous monitoring is always desirable, and in some cases necessary. In other cases, it may not be necessary or practical. You should monitor

often enough that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the critical limit. Additionally, the greater the time span between measurements, the more products you are putting at risk should a measurement show a deviation from a critical limit has occurred, because you should assume that the critical limit had not been met since the last "good" value. Even with continuous monitoring, the paper or electronic record of the continuous monitoring should be periodically checked in order to determine whether deviations from the critical limit have occurred. The frequency of that check should be at least daily, and more frequent if required in order to implement an appropriate corrective action.

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

## **STEP 15:** Establish corrective action procedures.

A corrective action must be taken whenever there is a deviation from a critical limit at a CCP (21 CFR 123.7((a)). For each processing step where a significant hazard is identified on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the critical limit has not been met. Note that the Seafood HACCP Regulation does not require that you predetermine your corrective actions. You may instead elect to follow the prescribed corrective action procedures listed at 21 CFR 123.7(c). However, a predetermined corrective action has the following advantages: (1) It provides detailed instructions to the processing employee that can be followed in the event of a critical limit deviation; (2) it can be prepared at a time when an emergency situation is not calling for an immediate decision; and (3) it removes the obligation to reassess the HACCP plan in response to a critical limit deviation.

The hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Establish Corrective Action Procedures," that provides information about appropriate corrective action procedures for each of the control strategy example(s) discussed. An appropriate corrective action procedure must accomplish two goals: (1) ensure that an unsafe product does not reach the consumer and (2) correct the problem that caused the critical limit deviation (21 CFR 123.7). If the corrective action involves testing the finished product, the limitations of the sampling plan should be understood. Because of these limitations, microbiological testing is often not a suitable corrective action. The Seafood HACCP Regulation requires that corrective actions be fully documented in records (21 CFR 123.7(d)). Note that if a critical limit deviation occurs repeatedly, the adequacy of that CCP for controlling the hazard should be reassessed. Remember that deviations from operating limits do not need to result in formal corrective actions.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

## **STEP 16:** Establish a recordkeeping system.

For each processing step where a significant hazard is identified on the HACCP Plan Form, list the records that will be used to document the accomplishment of the monitoring procedures discussed in Step 14 (21 CFR 123.9(a)(2)).

The hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Establish a Recordkeeping System," that provides information about appropriate records for each of the control strategy example(s) discussed. Records must document monitoring of the CCP and shall contain the actual values and observations obtained during monitoring (21 CFR 123.6(b)(7)) The Seafood HACCP Regulation lists specific requirements about the content of the records (21 CFR 123.9(a)).

Enter the names of the HACCP monitoring records in Column 9 of the HACCP Plan Form.

## **STEP 17:** Establish verification procedures.

For each processing step where a significant hazard is identified on the HACCP Plan Form, describe the verification procedures that will ensure that the HACCP plan is (1) adequate to address the hazard and (2) consistently being followed (21 CFR 123.6(c)(6)).

The hazards and controls chapters of this guidance (Chapters 4 through 7, 9, and 11 through 21) each contain a section, "Establish Verification Procedures," that provides information about appropriate verification activities for each of the control strategy example(s) discussed. The information covers validation of the adequacy of critical limits (e.g., process establishment); calibration (including accuracy checks) of CCP monitoring equipment; performance of periodic end-product and in-process testing; and review of monitoring, corrective action, and verification records. Note that the Seafood HACCP Regulation does not require product testing (21 CFR 123.8(a)(2)(iii)). However, it can be a useful tool, especially when coupled with a relatively weak monitoring procedure, such as reliance upon suppliers' certificates.

When calibration or an accuracy check of a CCP monitoring instrument shows that the instrument is not accurate, you should evaluate the monitoring records since the last instrument calibration to determine whether the inaccuracy would have contributed to a critical limit deviation. For this reason, HACCP plans with infrequent calibration or accuracy checks can place more products at risk than those with more frequent checks should a problem with instrument accuracy occur.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

## **STEP 18:** Complete the HACCP Plan Form.

When you have finished these steps for all 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 (21 CFR 123.6(d)(1)). It signifies that the HACCP plan has been accepted for implementation by your firm.