

APPENDIX

The HACCP Planning Process

A team approach to HACCP planning helps make sure important steps are not overlooked. Work with the biologists at your field station and the Regional Coordinator to develop HACCP plans.

Implement HACCP planning using the five-step process below:

Step 1—Describe the activity.

Step 2—Identify potential hazards.

Step 3—Diagram the sequential actions in step 1.

Step 4—Analyze the hazards identified in step 2 for each sequential action in step 3, and develop associated control measures.

Step 5—Complete the HACCP plan.

See page 4 for a glossary of terms we use in HACCP planning.

Step 1

Describe the Activity—See *FWS Form 3-2371-1 for a template*. This section should answer the who, what, where, when, how, and why of the project in one or two concise paragraphs. Describe the activity, the method of accomplishing the activity, and the intended purpose and need for the activity. Describe a discrete work action; do not try to cover all station operations and objectives. HACCP planning works best for specific actions, e.g., raising and stocking fish or conducting habitat surveys (aquatic and terrestrial).

Step 2

Identify Hazards—See *FWS Form 3-2371-2 for a template*. Identify the potential hazards and categorize them into four classes:

- vertebrates,
- invertebrates,
- plants, and
- others (e.g., diseases, pathogens, parasites).

This is primarily a brainstorming step and may require research on local risks beyond those immediately familiar to you. You should consider various life stages of organisms (e.g., spores, seeds). Biologists, agencies, organizations, and States may disagree on what significant hazards must be removed from specific pathways. Discussions here focus on planning objectives that establish the foundation for each HACCP plan. Completing Step 4, the Hazard Analysis Worksheet, will further sharpen the focus on non-target species that need to be removed from the pathway you are analyzing.

Step 3

Diagram the Sequential Actions in Step 1—See *FWS Form 3-2371-3 for a template*. Draw a flow diagram in block form to show the sequential tasks required to accomplish the activity. It is best to copy the simple, straightforward descriptions from Step 1. It is important to include all the tasks within the activity. The flow diagram should be detailed enough to characterize the activity or process for people reviewing the HACCP plan, but not so detailed that the subsequent steps are overly complicated. The HACCP Step 3 diagram (FWS Form 3-2371-3) suggests no more than 10 tasks.

Step 4

Analyze Hazards using Worksheet—See *FWS Form 3-2371-4 for a template*. Use the Hazard Analysis Worksheet to organize and document considerations you and your team identified as hazards.

- 1) Copy each task in your flow diagram (Step 3) to column 1 in this worksheet.
- 2) Copy potential hazards you identified in Step 2 to column 2.

- 3) Record risk assessment results in column 3.
- 4) Include the justification for accepting or rejecting each potential hazard stated in column 4.
- 5) List control measures in column 5.
- 6) Explain whether the task is a critical control point in column 6.

- **Analyzing Hazards—**

- Define control measures for each significant hazard you identify.
- Assess each potential hazard by considering risk (probability of occurrence) and severity.
- Base the estimate of risk on a combination of experience and of the pathway. Severity is the seriousness of a hazard.

In step 2, you identified potential hazards when brainstorming. In step 4, the team uses its list of hitchhikers, or non-targets, to evaluate the risks and severity of each of the hazards if they are unintentionally moved to a new habitat. Planners then decide which hazards are significant and must be addressed by the HACCP plan. Planning focuses on significant hazards reasonably likely to occur unless specific control measures are in place. Control measures are actions that you can use to prevent or eliminate a hazard or reduce it to an acceptable level.

A hazard must be controlled if:

- (1) it is reasonably likely to occur, and
- (2) if not properly controlled, it is likely to result in an unacceptable risk of spreading non-target species to new habitats.

- **Identifying Critical Control Points—**Every significant hazard you identify during the hazard analysis should have one or more critical control points where the hazard is best managed, controlled, or reduced through cleaning practices. Critical control points are points in the activity, or the pathway, where we use specified HACCP control actions to control significant hazards.

Many points in the flow diagram you do not identify as critical control points are still valuable control points where routine prevention measures help to achieve our goals. Only points you identify as key to control significant hazards are critical control points. Differentiating between critical control points and other control points varies from activity to activity and depends on the operation.

It may not be possible to fully eliminate or prevent a hazard. In some cases, minimization may be the only reasonable goal of the HACCP plan. Although hazard minimization is acceptable in some instances, it is important that you address all hazards so that resource management agencies and their partners understand any limitations of the HACCP plan to control hazards. When HACCP plans cannot satisfactorily control hazards, we must take other approaches to prevent the spread. Often, the best place to control a hazard is at the point of entry, but this is not always true. The critical control point can be several steps away from the point at which the significant hazard is introduced.

The critical control point decision tree provides a series of four questions to help you identify critical control points. You can find the decision tree in the Pathway Management manual on the support [Web site](#). The planning wizard on this Web site may help you distinguish critical control points from other control points.

- **Establishing Controls—**You should establish one or more controls for each critical control point you identify. Where controls are not technically feasible, further risk evaluation will be needed to determine if the activity is still justified. Where appropriate, you should communicate associated control development needs to research partners.

Step 5

Complete the HACCP Plan Form—See *FWS Form 3-2371-5 for a template*. From the Hazard Analysis Worksheet (Step 4), copy the critical control points from column 6 to the HACCP Plan Form. If you did not note any critical control points, then planning is complete.

The HACCP Plan Form describes techniques, methods, and treatments that will control the hazards identified in column 2. Monitoring specified critical limits can prevent the need for corrective action because you can change treatments before you exceed a critical limit. Accurate records provide verification that HACCP procedures are effectively controlling hazards.

- **Setting Critical Limits**—Define control boundaries or limits to ensure non-targets are removed or prevented from entering the pathway. If the process deviates from the limits you established for the control, you must take corrective actions to make sure that non-targets do not slip past a critical control point.

You use testing combined with scientific information to establish critical limits. This reference material should become part of the HACCP Plan support documentation. The team usually recommends controls that can be quantified and measured in concentrations, units of time, or amounts of something for control effectiveness. Variations from these specifications would mean that contaminating species (hitchhikers) could slip through established controls.

Research limits and clearly document them during planning so those implementing the HACCP plan generated in step 5 can effectively monitor efforts to avoid costly errors.

- **Monitoring**—Control limits are meaningless if not monitored for compliance. You should document in the HACCP plan the type of control limit monitoring needed, how it will be accomplished, by whom, and how frequently.
- **Corrective Actions**—You usually address corrective actions in an “if/then” format in the plan. You implement corrective actions to re-establish control as soon as monitoring indicates that a control limit has been or may be breached. Corrective action should take care of immediate problems as well as provide long-term solutions. Routine critical limit failure means you need to update the HACCP plan.
- **Supporting Documentation**—The HACCP Plan Form has a column to note where supporting documentation regarding verification and records can be found.
- **Verification and Validation**—Verification is important in HACCP planning and execution. Verification ensures that procedures at critical control points are functioning. Regular review of calibrations, monitoring results, and corrective action records lets managers know if operating limits are removing non-target species. Verification should include tests to check that HACCP plans are working and being followed.

In addition to verifying critical control points, HACCP planners should identify scheduled verification of the complete HACCP system. Validation, a component of verification, provides objective evidence that the plan is based on scientific information representing a valid approach to control spread of non-target species through resource management pathways. The HACCP team or outside reviewers should validate plan components before relying on the HACCP plan to control hazards. Regularly review and update planning strategies to incorporate new techniques.

Building a National Database of HACCP Plans—HACCP planners have an opportunity to contribute to the science of natural resource work. Comprehensive HACCP plans document best management practices that describe methods and procedures used to prevent and remove non-target species. Sharing best management practices will help others doing similar work. A web-based reference library has been established so that shared plans can be easily searched for methods and procedures. Best management practices are readily available in a database for other resource managers who may be addressing similar problems. This database is available on the [HACCP Web site](#). Because some of the HACCP plans posted in this library have not gone through standardized peer review, they may not include thorough information on controls or control limits.

GLOSSARY

The following definitions are how we use the terms for HACCP planning.

- Control
 - verb—to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.
 - noun—state where correct procedures are being followed and criteria are being met.
- Control measure—any action and activity or tool that we can use to prevent or eliminate a hazard or reduce it to an acceptable level.
- Corrective action—any action we take when the results of monitoring at the critical control point indicate a loss of control.
- Critical control point—a step at which control can be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level.
- Critical limit—a criterion that separates acceptability from unacceptability.
- Deviation (from critical limit)—failure to meet a critical limit.
- Hazard Analysis Critical Control Point (HACCP)—a system that helps us to identify, evaluate, and control hazards that are significant for a wide range of natural resource management applications.
- HACCP plan—a document we prepare in accordance with the principles of HACCP to ensure control of hazards.
- Hazard—a biological, chemical, or physical agent or condition that may cause an unwanted or adverse effect in an exposed system.
- Hazard analysis—the process of collecting and evaluating information on hazards and conditions leading to their presence and necessary to include in a HACCP plan.
- Invasive species—an alien organism whose introduction does or is likely to cause economic or environmental harm or harm to human health.
- Monitor—the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control.
- Non-target species—plants, animals, diseases, pathogens, parasites, or biologics that we do not intend to move.
- Pathway—both natural and man-made, are the means by which organisms are transported from one location to another.
- Target—the specific organism or product being moved.
- Validation—obtaining evidence that the elements of the HACCP plan are effective.
- Verification—the application of procedures, tests, and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.