

## Module 3: Steps in the Development of the HACCP System and Relationship of HACCP/CGMPs/SSOPs

- Goal** The goal of this module is for the trainee to have a working knowledge of HACCP systems development and the relationship of CGMPs and SSOPs and to impart an understanding of the variety of ways that industry might approach regulatory compliance.
- Objectives** After completing this module, participants will be able to recognize how the industry may:
1. Evaluate a HACCP specific plan for the presence of “preliminary HACCP” steps used in the creation of the HACCP specific plan. They could include:
    - a. Bringing together HACCP resources. **Page 10**
    - b. Describing the product and its method of distribution. **Pages 11-12**
    - c. Developing a complete list of ingredients and raw materials used in the product. **Page 13**
    - d. Developing a process flow diagram. **Pages 14-15**
    - e. Meeting the regulatory requirements for Sanitation Standard Operating Procedures (SOPs). **Page 16**
    - f. Needing Hazard Analyses for specific processes. **Page 16**
  2. Use a scientific process to identify Critical Control Points (CCPs). **Pages 17-33**
  3. Establish Critical Limits for each identified CCP. **Pages 34-36**
  4. Establish monitoring procedures to ensure that preventive measures necessary for control at each CCP are maintained within the established critical limits. **Pages 37 and 38**
  5. Establish specific corrective actions for each CCP. **Pages 39 and 40**
  6. Establish recordkeeping procedures to verify that the HACCP plan is working. **Pages 41 and 42**

7. Establish procedures to verify that the HACCP plan is working correctly. **Page 43-49**
8. Implement verification procedures to ensure that each CCP and critical limit is adequately controlled and monitored. **Page 43**
9. Implement, for each CCP, procedures to ensure that employees are following established procedures for handling product deviations and for recordkeeping. **Page 43, paragraph 2**

Also, upon completion of the training, participants will be able to:

10. Describe how industry might incorporate quality/operating limits along with CCPs. **Page 29**
11. Differentiate between CGMPs, SSOPs, and HACCP. **Page 29**
12. State which are requirements, as opposed to recommendations. **Throughout module**
13. Describe the variety of ways that industry may develop plans that meet regulatory requirements. **Throughout module**

- Steps**
- Introduce the module
  - Show the videotape
  - Discuss answers to fill-in-the-blank questions

**Instructions to Facilitators**

Display the objectives on the flipchart and review them with participants.

Inform participants that the format for this module is to:

- Orient participants to the Participant's Guide
- Watch the videotape
- Follow along in the participant's handout if desired
- Fill in blanks on the worksheet for discussion after viewing the tape

Tell them answers to the worksheet are in both the tape and the guide.

**Announce that the video will be paused, and questions discussed in segments.**

Instruct participants to fill in blanks after watching the video.

Briefly orient participant's to the Participant's Guide

In your own words, make the following points before the video:

This module presents an example of steps that industry may use in developing HACCP plans. This is industry perspective, not FSIS requirements.

This is typical of what consultants and organizations present to industry in workshops for HACCP—they present each step and establishments fill them in as they go until the plan is completed.

Notice that the numbering of principles 1–7 is different from the Agriculture Canada videotape. The principles are the same.

Emphasize the forms are **example forms only, not required**.

Emphasize that there are many ways that industry may develop their plan.

Reemphasize these are **NOT** FSIS requirements—those will come later.

=====

Show the video. You may pause and review as you feel appropriate.

1. After Preliminary Steps discuss questions 1-2.

2. After Hazard Analysis discuss questions 3-8.

3. After Critical Control Points and Critical Limits discuss questions 9-16.

4. After remainder of video discuss questions 17-22.

=====

After the videotape, use the following questions to lead the group discussion. If necessary, refer to the guide for clarification.

Answer key, with key points to emphasize:

1. The five preliminary steps are:
  - a. **gather resources**
  - b. **describe product and distribution**
  - c. **list ingredients and raw materials**
  - d. **develop process flow chart**
  - e. **establish SSOP's**
  
2. The preliminary steps which the establishment is required to do, are **SSOP and develop a process flow chart.**

Key Point: preliminary steps—SSOP and the process flow chart are **required.**

3. The seven HACCP principles are:
  - a. **Hazard analysis**
  - b. **Critical control points**
  - c. **Critical limits**
  - d. **Monitoring**
  - e. **Corrective actions**
  - f. **Recordkeeping**
  - g. **Verification**

4. An example of a biological hazard is **E. coli, etc.**
5. An example of a chemical hazard is **pesticide, etc.**
6. An example of a physical hazard is **broken glass, etc.**
7. Hazard analysis includes evaluating both the likelihood and **severity** of the hazard.
8. Each hazard that is listed should also have a **preventive** measure identified.

Key Point: hazard analysis—can cause harm and is reasonably likely  
—includes preventive measure for hazard

9. When a logical decision process is applied to a process step at which a hazard exists, plus preventive measures can reduce or eliminate the hazard, then that step is a **critical control point.**
10. Different establishments preparing the same product can differ in the number and location of their critical control points.  
 True                       False

Key Point: critical control point—based on logical decision process  
—emphasize the "Decision Tree" **not required**

\*\*Discuss here that sometimes steps that are determined not to be CCP's are then incorporated into the establishment's GMP's (Good Manufacturing Practices). This is because the step was determined to have a hazard even though the decision process determined it was not a CCP. GMP's are not required.

11. Some examples of critical limits are **time, temperature, humidity, water activity, pH, salt or chlorine concentration.**
12. Companies are permitted to set a critical limit that is different from a regulatory requirement provided it is based on **sound scientific data.**

Key Point: critical limit—CL is value set to **control hazard.**

\*\*Discuss here that an **operating limit** may be set which is more restrictive than the critical limit, and helps avoid reaching the critical limit. For example, an operating limit of 162 degrees for a critical limit of heating to at least 160 degrees.

\*\*Discuss here that a critical limit could be **"lowering to a certain level."** For example, withdrawing animals from antibiotic before slaughter to ensure drug residues are below the acceptable limit. (Facilitator—this concept was added by special request).

13. An example of continuous monitoring is **automatic time/temperature equipment.**
14. An example of noncontinuous monitoring is **visual observation, measuring water activity, measuring temperature, etc.**
15. The (**establishment?** , **FSIS?**) is responsible for establishing the monitoring frequency that ensures that the CCP is under control.
16. Corrective actions are planned in advance to correct deviations from **critical limits.**
17. Two examples of corrective actions are **adjust the process, hold the product, stop the line, use an alternate process.**

Key Point: corrective actions—the establishment **must do what it says!**

18. Two reasons why recordkeeping is important are **it documents compliance, tracing back problems, identifying trends, recalling product.**

19. Establishments may develop and use their own forms for the records they keep.  
 True                       False
20. Verification goes beyond monitoring to determine that the HACCP system is working as intended.  
 True                       False
21. Three examples of what the establishment may do to verify its plan are **audit monitoring procedures, calibrate equipment, sample product, review monitoring records, review dispositions, inspect plant operations.**
22. At least annually, and any time changes occur that could alter the plan, the HACCP plan should be **reassessed.**

Summary—Emphasize key points:

The plan is done by the establishment—we do not approve. We do “help” by answering questions.

A separate plan is done for each process. Similar products may be produced under the same plan.

Emphasize again that none of the forms are required—they are examples of what establishments may develop for their own use. Inspectors will likely see many types of in-house forms. FSIS requirements are presented later.

The Participant’s Guide is for reference as you encounter HACCP plans where you work. It is representative of what industry might use, but there are many others that industry could also use.

Remind participants that inspection requirements come later in the training.

Note that the people interviewed on the tape are not plant managers, but they do represent plants.

Industry has received information from FSIS about certain expectations of the agency and clarification of questions about the HACCP plans that industry develops. Tab 12 in this notebook contains the following information that you may find useful as training proceeds:

- Livestock Carcasses and Poultry Carcasses Contaminated With Visible Fecal Material (Federal Register Vol. 62, p. 63254, 1997)
- Contents of HACCP Plans (Federal Register Vol. 63, p. 4562, 1998)
- Contents of HACCP Plans; Critical Control Points (Federal Register Vol. 63, p. 4560, 1998)
- Establishment Review of Product Production Records (Federal Register Vol. 63, p. 11104, 1998)
- HACCP Plan Requirements and Meat and Poultry Product Processing Categories; Policy Clarification (Federal Register Vol. 63, p. 15739)
- HACCP Hotline Trends: Inspection Personnel Questions on HACCP Implementation, Q&A #1, March 1998
- HACCP Hotline Trends: Industry Questions on HACCP Implementation, Q&A #2, June 1998

Indicate that these will be discussed further in Module 7.