

Applying For a Grant of Inspection - Hazard Analysis and Critical Control Points (HACCP)

NOTE: HACCP would not apply to Egg Products Plants

A. Conduct a Written Hazard Analysis

Before being granted Federal inspection, an establishment shall have conducted a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventative measures the establishment can apply to control those hazards.

Refer to 9 CFR 417.2 (a)(1)

B. Develop a Flow Chart

Every establishment shall prepare a flow chart describing the steps of each process and product flow in the establishment, and the intended use or consumers of the finished product shall be identified. A "step" is a point or activity in an operation within the production process that is essential to the proper production of the finished product. It is up to each establishment to identify these steps that are essential to their operation. Each step must be included on the flow chart. Multiple activities can be incorporated into one step. For example, in a ground beef patty operation, the establishment may determine that in their operation, the step of "processing" includes distinguishable activities that must be performed such as boning, grinding, forming, packaging and chilling. The establishment would need to consider whether there are any biological, chemical, or physical food safety hazards associated with the collective activities at the processing step. [\[417.2\(a\)\(2\)\]](#)

Refer to 9 CFR 417.2 (a)(2)

C. Develop a Written HACCP Plan

Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur within the production process. The contents of a HACCP plan are addressed in 9 CFR 417.2 (c) (1) to (c)(7)

Refer to 9 CFR 417.2 (b) and 417.2 (c)(1) to (c)(7)

D. Corrective Actions

The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

- (1) The cause of the deviation is identified and eliminated;
- (2) The CCP will be under control after the corrective action is taken;
- (3) Measures to prevent recurrence are established; and
- (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

Within the written HACCP plan, the establishment can simply state (for example): "Should a deviation from a critical limit occur, all four parts of 417.3 (a) will be met", and the establishment has met regulatory requirements. The establishment is not required to address "unforeseen hazards" in their HACCP plan.

Refer to 9 CFR 417.3 (a), (b), and (c)

If the establishment incurs a deviation not covered by a specific corrective action, or if another unforeseen hazard arises, the establishment shall:

Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met; (2) Perform a review to determine the acceptability of the affected product for distribution; (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce; (4) Perform or obtain reassessment by an individual trained in accordance with Section 417.7, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

Refer to 9 CFR 417.3 (b) and (c)

E. Validation, Verification, and Reassessment

Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis and shall verify that the plan is being effectively implemented. Ongoing verification activities may include the calibration of process monitoring instruments, direct observations of the monitoring activities and corrective actions and a review of records generated and maintained in accordance with 9 CFR 417.5 (a)(3). Every establishment shall reassess the adequacy of their HACCP plan at least annually and whenever any change has occurred that could affect the hazard analysis or HACCP plan.

Refer to 9 CFR 417.4

F. HACCP Records

Every establishment shall maintain records documenting the establishment's HACCP plan and decision-making documents associated with the selection of the CCP's, CL's, monitoring and verification procedures and frequency of those procedures. In addition, the establishment is required to provide all supporting documentation for the decisions made in their hazard analysis. When making an entry onto an official HACCP record, each entry shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

NOTE: You may utilize an outside consultant who is not employed by the establishment to conduct your HACCP functions for you. Questions about the use of consultants may be answered by an FSIS representative.

There are some operators who don't have access to the Web or aren't sure about the question they need to ask, or really need to talk to someone, or have questions about available resources. Based on that information, FSIS established a Small Plant Help Desk team to assist new operators that are planning to come under FSIS jurisdiction or just getting started. The purpose is to be a one-stop shop for small operators who have questions. They will be able to field every type of question, even labeling. They may not answer each question but will direct the caller to the appropriate FSIS program area.

Hours of operation: 8am-4pm EST, although they may be able to set up appointments outside those hours (especially for those operators located on the west coast or Hawaii).

The FSIS Small Plant Help Desk Staff will be available to answer phone and email inquiries at 1-877-FSIS HELP (1-877-374-7435) or InfoSource@fsis.usda.gov. Phone messages or email inquiries can also be submitted outside these hours and a staff specialist should follow up with you within one business day.

This is NOT a replacement for “askFSIS” – which is still the place to go if you want policy answers to FSIS related issues. *askFSIS* can be accessed by following the link provided:
<http://askfsis.custhelp.com>.

The FSIS home page has several generic HACCP model plans available, based on the different processing or slaughter category, which can be reviewed by accessing the link below.

http://fsis.usda.gov/Science/HACCP_Based_Inspection_Models/index.asp

With State inspected establishments, each State has also assigned a HACCP Coordinator to assist plant management with the development of their HACCP Programs.

http://www.fsis.usda.gov/Regulations_&Policies/State_Inspection_Programs/index.asp