

Questions and Answers Related to Performance of the Hazard Analysis Verification (HAV) Task

1. Q. Do establishments need to meet new requirements once inspectors start performing the Hazard Analysis Verification (HAV) task?

A. No. Under the HAV task, inspection program personnel focus on verifying that establishments have addressed the appropriate hazards for their production processes as required by 9 CFR 417.2 and that they maintain supporting documents for the decisions in their hazard analysis as required by 9 CFR 417.5(a). Prior to establishing the HAV as a separate inspection task, IPP verified these requirements as part of the HACCP implementation tasks.

2. Q. Why does FSIS believe it is necessary to focus IPP on verifying establishments' hazard analyses?

A. FSIS believes that by focusing IPP verification on the hazard analyses, they will be able to identify any problems with the hazard analysis much earlier than would be the case if the Agency had to wait until the next FSA to identify such problems. Establishments will then be able to correct such problems and ensure that they are addressing the applicable food safety hazards for their products.

3. Q. What is the frequency at which the HAV will be performed?

A. Routine HAV tasks will be performed on a quarterly basis (one per three months). IPP will schedule when to perform the HAV within the quarter as they plan their inspection task calendars with the other verification tasks they routinely perform.

4. Q. Can there be directed HAVs scheduled at a more frequent basis?

A. Yes, FSIS may schedule directed HAVs once per month at specific establishments based specified criteria, for example, when there is a question about whether an establishment has conducted an adequate hazard analysis (e.g., when there are repetitive noncompliance determinations or positive FSIS lab samples). The Agency may also decide to task IPP to perform directed HAVs at establishments that produce specific products, or when the Agency decides that protection of the public health requires that a HAV be conducted.

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5. Q. Are there new enforcement actions that the Agency will impose on establishments based on the findings of a HAV task?

A. No, the HAV task will not in itself create any new regulatory requirements or enforcement actions. However, through the HAV, IPP may uncover noncompliance with the Agency's regulations. If such is the case, the Agency will initiate the appropriate enforcement action in the same way that it does now.

6. Q. How does the HAV differ from the HACCP verifications that inspectors have been doing?

A. Through the HAV, IPP specifically concentrate on verifying that the establishment has conducted its hazard analysis in accordance with the applicable regulatory requirements. IPP are also to consider what their findings show about the overall effectiveness of the establishment's food safety system by verifying that the establishment has met regulatory requirements by considering whether the hazards relevant to its products are reasonably likely to occur in its operation and addressing those hazards that are. If IPP have concerns about the ability of the establishment's food safety system to produce safe products, they are to discuss those concerns with their supervisor. In contrast, the HACCP verification tasks focus on verifying the establishment's ability to implement the written HACCP plan.

7. Q. Are HAV tasks expected to take longer to perform than other inspection tasks?

A. Yes. Because the HAV procedure includes a careful review of an establishment's documentation related to its hazard analysis, as well as observation of the establishment's implementation of its prerequisite programs, the Agency estimates that that the time it will take IPP to perform the HAV will be considerably longer than other routine inspection tasks. The actual performance time will vary depending on the number of hazard analyses and HACCP plans, and the complexity of the hazard analyses and prerequisite programs, at a particular establishment. An employee may discuss scheduling with his or her supervisor, if necessary, for assistance in determining how to allot sufficient time to perform the HAV, while still accomplishing other high priority food safety verification tasks.

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8. Q. Who will perform the HAV at an establishment?

A. Consumer Safety Inspectors (CSI) will ordinarily perform the HAV task. However, in slaughter or combination establishments, Public Health Veterinarians (PHV) may also perform HAVs or supervise CSIs performing HAVs.

9. Q. Is the HAV an abbreviated version of a Food Safety Assessment (FSA)?

A. No, the HAV is not an FSA. IPP will conduct the HAV to verify that an establishment meets the regulatory requirements related to the development and implementation of the hazard analysis, and that the establishment has addressed the relevant food safety hazards for all the establishment's processes, products, and intended uses in accordance with 9 CFR 417.2(a). IPP will identify obvious cases of noncompliance and other issues of concern that may require further consideration or investigation by an Enforcement, Investigations, and Analysis Officer (EIAO). In contrast, when EIAOs perform FSAs, they verify the design of the HACCP system in addressing and controlling food safety hazards. In verifying the design, they verify that the establishment can support its decisions in identifying appropriate hazards and in deciding how to control the hazards that are reasonably likely to occur. At the conclusion of the FSA, the EIAO is expected to write a supportable Agency position concerning whether the establishment's HACCP system is designed to control hazards associated with the process.

10. Q. When a CSI performs an HAV, could the findings lead to an FSA?

A. Yes. If the findings of a HAV raise questions about the design of a HACCP system in controlling food safety hazards, the Agency will have an EIAO conduct an FSA to fully evaluate the establishment's food safety system.

11. Q. It has been a while since IPP have attended PHIS training and the scheduling of the HAV task. Will IPP be provided any refresher training? Are inspectors prepared to perform the HAV?

A. The directive covers the topics that were covered in the training all inspection program personnel received and provides additional clarification. The directive also includes links to document other resources, such as the hazard control guide and training materials. FSIS will also provide time for CSIs to review the policy document and instructional material.