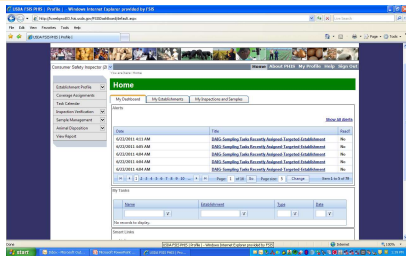


Documenting the FSA



1

PHIS



2

FSA Documentation

- Use appropriate FSA tools in PHIS
- Copy of Tools can also be obtained from FSIS website
<https://www.fsis.usda.gov/inspection/compliance-guidance/food-safety-assessments-tools>
- Do not keep notes outside tools as they may be evidence

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Noncompliance

- Noncompliance observed during the FSA will always be documented in the FSA report.
- Additionally, noncompliance will be documented in either an NR or it may be included in an enforcement letter (NOIE or NOS).

Noncompliance

- Example:
 - EIAO determines the establishment failed to identify a step in the flow chart.
 - This is regulatory noncompliance, but it may not pose an immediate health risk.
 - It would be prudent to complete the assessment process to determine how the matter should be addressed (NR or part of an enforcement letter if other noncompliance exists).

Noncompliance

- If additional noncompliance is observed during the FSA and an NOIE is warranted:
 - The NOIE documents noncompliance findings supporting the proposed action.
 - Other noncompliances that are not in support of the NOIE would be documented on NRs.
 - All enforcement letters and NRs are presented to the establishment at the exit meeting.

Noncompliance

- If no enforcement is warranted, any noncompliance would documented on NRs.
- Work with the FLS and IPP to assure NRs are presented at the exit meeting.

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Noncompliance

- FSIS must first stop the practice and take a RCA immediately if an establishment is:
 - shipping or producing adulterated product,
 - operating without a HACCP plan
 - treating animals inhumanely
 - engaging in any other type of noncompliance that supports taking action under the Rules of Practice
- A NR should be issued to the plant ASAP

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Noncompliance

- For immediate enforcement, correlate with the IPP, the FLS, and the District Office.
- If a suspension without notice is warranted, the NR can serve as a basis to support the action .
- The Food Safety Assessment can be completed later during the enforcement process.

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Noncompliance

- Anytime noncompliance is observed, it is important to bring it to the establishment's attention and discuss it as soon as possible.



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Noncompliance

- Whenever noncompliance is discussed with the establishment:
 - Document what was discussed, including when the discussion took place and who was present.
 - The written summary can be part of the FSA or a separate memorandum for the record.
 - It is important in the administrative record to support that noncompliance was brought to the establishment's attention in a timely manner.

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Noncompliance

- When notified of noncompliance that is not part of an enforcement action:
 - The establishment may take action to bring themselves back into compliance
 - An NR will still be documented and presented at the exit meeting
- This is why it is important to document that the establishment was notified, in the FSA or in an MOI.

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Noncompliance

- NRs are fundamental “building blocks” to effective enforcement.
- They assure establishments have been provided the opportunity to correct situations before enforcement becomes necessary.



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Noncompliance

- EIAO should reiterate with inspection team importance of documenting noncompliance, associating NRs, and building a case
- Being able to show history of multiple, recurring noncompliances is an important factor to support issuing a NOIE
- When suspending the assignment of inspectors without notice, documentation must exist to support action is warranted.

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Follow-up

- Work with FLS to determine whether noncompliances require a follow-up
- Document need for follow-up in General Tool
- Contact the FLS within 30 days of the exit meeting to determine status of the NR

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