

EVALUATION REPORT

Feedback on Notice 29-02 HACCP Verification Procedures and 30-Day Reassessment Letter September 2002

Purpose

This report presents results of an evaluation of *Notice 29-02: HACCP Verification Procedures and the 30-day Reassessment Letter* issued August 9, 2002. The purpose of the evaluation is to assess the clarity of the Notice and provide recommendations for its reissue.

Method

The original plan for this evaluation was to survey users to obtain their feedback on the Notice's clarity and usefulness. However, when reviewing the Notice in preparation for designing the survey, many issues were noted that did not warrant a survey to support. Considering this fact in addition to providing timely feedback and reducing respondent burden, the following evaluation is based on a critical review of the Notice by the Program Evaluation and Improvement Staff. The review focuses on determining if the body of the Notice clearly identifies the following essential components to provide satisfactory instruction to the field: title, responsible parties, inspection procedures, required actions, time frames, references, accountability measures and enforcement actions. The format is also addressed.

Key Findings

- Title and purpose do not convey clearly the contents of the Notice.
- The Question and Answer format does not provide easy to follow directions.
- The order of the contents as presented is confusing and it is not clear why directions for the 30-day reassessment letter are included with the rest of the Notice.

- Notice uses terminology that is not clear and requires additional knowledge of regulations and inspection procedures that, if not known, would require time and effort to obtain.
- Notice does not identify the specific inspection personnel to carry out specific procedures and actions.
- Notice does not identify relevant accountability and enforcement actions.

Recommendations

- Ensure title and purpose clearly describe the contents of the Notice.
- Put 30-day reassessment letter provisions in a separate notice that includes all uses.
- Reorganize the contents to present items in the order listed in the purpose with record review verification procedures described before listing findings and actions for deviation from a critical limit and nonconformance.
- Use format for each section that:
 - has an informative title,
 - bullets appropriate actions, and
 - links specific personnel with actions.
- Provide definitions or references for terms used such as “corrective”, “required” and “expected” actions by the establishment.
- Provide reference citation and text in footnotes or attachments for an audience that includes new and old employees.
- Specify inspection personnel to perform inspection procedures and enforcement actions. Define more clearly:
 - role of Technical Services Center,
 - role of Consumer Safety Officer, and
 - methods to identify a trend.
- Provide time frames for actions – define terms such as immediate.
- Include accountability steps for District Manager to ensure adherence.

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Findings and Recommendations by Section

Title

Title does not accurately describe contents of the notice. The notice includes information on:

- record review in 01 and 02 HACCP verification procedures,
- identifying deviations from the critical control point and noncompliance,
- appropriate actions to these findings,
- use of the 30-reassessment letter.

However, the title, *HACCP Verification Procedures and the 30-Day Reassessment Letter*, does not mention all these items. Furthermore, the contents of the Notice do not address all components of HACCP verification as defined in 9CFR 417.8¹: it stresses only the record review portion of verification (items e & h). As related to the 30-day reassessment letter, it also addresses only one possible use: to address concerns about the scientific and technical basis for the design of an establishment's HACCP plan. Inspectors reading the title and notice would still have questions about items in the title not addressed in the Notice.

Recommendation

- Revise title to reflect the contents of the Notice.

Section I. What is the purpose of this notice?

The purpose is not clearly stated and does not mention all items included in the Notice. The contents of the Notice do not follow the order

¹ Verification may include: (a)Reviewing the HACCP plan; (b)Reviewing the CCP records; (c)Reviewing and determining the adequacy of corrective actions taken when a deviation occurs; (d)Reviewing the critical limits; (e)Reviewing other records pertaining to the HACCP plan or system; (f)Direct observation or measurement at a CCP; (g)Sample collection and analysis to determine the product meets all safety standards; and (h)On-site observations and record review.

of the purposes listed. The contents jump back and forth between record review activities, not listed as a purpose, and identifying and responding to noncompliance and deviations from a critical limit, listed as a purpose but not included in the title.

Recommendations

- List all intended purposes in bullet form.
- Combine (current) Sections II B and D that address record review in HACCP verification and place first in Section II. Follow with (current) Sections II A and C that address deviation from a critical limit and noncompliance.
- If this is a follow-up to elaborate or correct a previously issued directive or notice, include that reference.

HACCP Verification Procedures

Section II Background A

Definitions and references included do not clearly define the difference between the expected and required actions that a deviation from a critical limit or a HACCP noncompliance trigger by the establishment. Regulations referenced call for “immediate action”, a time frame that is not defined.

Recommendations

- Attach text for references from 9CFR 417.3 and FSIS Directive 5000.1 for deviation from a critical limit, and HACCP noncompliance.
- Use a clear and consistent format to describe how to determine a finding and the appropriate actions by all interested parties.
- Include definitions or references for terms such as corrective, expected, required and immediate.
- Include time frames with actions.

One possible format, shown in italics below, includes bullets to define how to determine findings followed by a list of the actions by the

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establishment and specific inspection personnel with time frames.

To determine a noncompliance, the inspector identifies the following:

-
-

For a noncompliance,

The establishment does the following:

-
-

The inspector does the following:

-
-

The DM does the following :

-

An alternative format is a table listing findings and actions like the following.

<i>Finding</i>	<i>Action</i>
Nonconformance	The inspector does
	The establishment does
	The DM does

Section II B

This section is confusing in its current placement between two sections on deviation from a critical limit and nonconformance.

Recommendations

- Reorder sections as recommended above.
- Attach references from 9CFR 417.8 for verification record review.

Section II C

The format used to determine a noncompliance is not clear and is different from the format used to describe a deviation from a critical limit and the appropriate actions in section II A. It mentions but does not include instructions on how to determine a trend.

Recommendations

- Combine with Section II A as recommended above and use same format.

- List steps to determine existence of a trend.

Section II D

This section belongs earlier in the Notice with the description of the 01 HACCCP verification procedures. It is not clear whether there are any follow-up actions and specific inspection personnel to perform them.

Recommendations

- Combine with Section B as recommended above.
- List follow-up actions, if any, with time frames and specify inspection personnel to conduct them.

Section III

The examples are helpful but interrupt the flow of the Notice. They include regulatory references that require the reader to research the actual wording.

Recommendations

- Put the examples in an appendix.
- Attach actual wording for referenced regulations and directives.

Section IV – 30-Day Reassessment Letter

This section does not flow naturally from the above section. Some background on why this is attached would be helpful such as the HACCP provisions for individual initiative to address local concerns which have included meeting with establishment personnel and a letter requesting response within thirty days.² This section is further confusing because it limits the direction of the 30-day reassessment letter to concerns about the scientific and technical basis of an establishment's HACCP plan instead of full findings of record review

² Recent notices such as *Notice 28-02* (July 25, 2002) and the April 2002 *In-plant Performance System Supervisory Guidelines* provide written instructions on the use of a 30-day letter.

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verification. It mentions but does not define the role of the Technical Service Center and the Consumer Safety Officer. It does not specify who issues the 30-day reassessment letter.

Recommendations

- Provide background on the 30-day reassessment letter and why it is included in this notice.
- If the 30-reassessment letter does not relate to the record review verification focus of the rest of the Notice, consider

putting it in a separate notice that would list other appropriate uses of the 30-day letter for record review verification.

- Identify inspection staff to issue 30-day reassessment letter.
- Provide suggested format for letter.
- Define role of Technical Service Center staff and Consumer Safety Officer.
- List further suggested actions if there is no response to the 30-day reassessment letter.