Writing EIAO Correspondence

Course Objectives

- Adopt important “Plain Language” writing principles.
- Use best practices in email writing.
- Write clear, logical, easily understood FSA tool question responses, analyses, and executive summaries.

Key Ideas

1. Always have a point that can be expressed in about 10 words or fewer, and put that bottom-line up front (BLUF) at the start of paragraphs, analyses, and summaries.

2. Write for people who “live outside the neighborhood”— in other words, for people unfamiliar with the document and the issue or issues within it.

3. Maintain focus and scope by eliminating irrelevant content.

4. Use shorter sentences (15-20 words) and active voice to enhance your reader’s understanding. Shun “tion.”

5. “Chunk” information with headings to enhance your readers’ understanding.

Desk Tool: Writer's Process and Checklist

Set Goal

1. Ask and answer: Why am I writing this document? What is the outcome I am seeking?

Consider Audience

2. Ask and answer: Who is the audience? What do I know or need to know about the audience?

   Consider the audience's knowledge, values, whether internal or external, authority level, anticipated reaction, personal preferences, cultural norms, expectations, political or budgetary constraints, and priorities.

Optimize Content

3. Ask and answer: Based on the purpose and the target audience(s), what content do I need to include? Distinguish between must-have and nice-to-have content. What is the best format? Create an outline, as appropriate.

Produce Message

4. Write your document.
5. Let your writing "cool." Do not review or edit it for at least an hour, but longer if possible.
6. Edit and proofread your document. Use MS Word's spelling and grammar check and the Writer's Checklist to ensure you have used clear, succinct language. Revise the document as necessary.

Evaluate Success

7. Evaluate the success of your written document. Did you get what you were seeking?

The Writer's Checklist

Have you done the following?

1. Identified a specific goal and considered the audience before writing?
2. Led with your request or your main idea?
3. Created an outline that logically presents the content?
4. Used "roadmap" sentences and paragraphs to guide readers?
5. Included an introduction in longer documents, with a synopsis and guidance on using the document?
6. Used plain, accessible language?
7. Written predominantly short sentences, averaging 15-20 words?
8. Used bullet points and other organizational techniques to break up text?
9. Used verbs in place of nouns, where possible (i.e. "verify" instead of "verification")?
10. Predominantly used active voice, and used passive voice only when preferred?
11. Ensured positive or neutral tone in your document?
12. Used linking words and phrases to transition between ideas and paragraphs?
13. Ensured lists are in parallel structure?
14. Ensured consistency in capitalization?
15. Correctly introduced and punctuated initialisms, acronyms, and abbreviations?
16. Read the entire message or document for accuracy, clarity, and positive or neutral tone?
17. Included lists of acronyms and defined terms when needed?
18. Ensured graphs and charts have context and clear takeaway messages?
19. Used greetings, closings, pronouns, and complete sentences in email messages?
20. Started with a fresh template rather than reusing an existing document when appropriate?

Plain Language Defined

President Barack Obama signed the “Plain Writing Act of 2010” on October 13, 2010. The Act is designed "to improve the effectiveness and accountability of Federal agencies to the public by promoting clear Government communication that the public can understand and use."

Tips for Using Plain Language

Certain qualities characterize plain language. These include common, everyday words, except for necessary technical terms. Other qualities include the use of personal pronouns; the active voice; logical organization; and easy-to-read and understandable design features, such as bullets and tables.

1. **Engage Your Readers.**

    - First, consider who your readers are.
    - Consider what your readers need to know and want to know. Organize content to answer their questions.
    - Write at a reading level that is appropriate to your intended audience.

2. **Write Clearly. Use common, everyday words whenever possible.**

    Word Choices

    - Use common, everyday words but avoid slang.
    - Use personal pronouns such as "you."
    - Use "must" instead of "shall."
    - Avoid using undefined technical terms.
    - Use positive rather than negative words.
    - Avoid using gender-specific terminology.
    - Avoid long strings of nouns.

    Verb Forms

    - Use active voice.
    - Use action verbs.
    - Use the present tense whenever you can.

    Structure

    - Use parallel construction.
    - Be direct.
    - Avoid unnecessary exceptions.

3. Display Material Correctly.

Appearance is an important aspect of clear communication. If a document is pleasing to the eye, it will be more likely to attract your readers' attention. Appearance can also be an aid to readers, improving comprehension and retention.

- **Organization.** Strong, logical organization includes an introduction followed by short sentences and paragraphs. Organize messages to respond to your readers' interests and concerns.

- **Introduction.** In lengthier documents, use an introduction and a table of contents to help readers understand how a document is organized.

- **Short Sentences and Paragraphs.** Sentence length should average 15-20 words. Sentences that are simple, active, affirmative, and declarative hold readers' interest. Generally, each paragraph should contain only one topic. You may wish to use a series of paragraphs if you need to express complex or highly technical information. The more writing deviates from a clear and to-the-point structure, the harder it will be for readers to understand what you are trying to convey.

- **Layout.** Layout includes margins, headings, and white space. Provide white space between sections to break up text and to make it easier for readers to understand. Use headings to guide readers; the question-and-answer format is especially helpful. Try to anticipate your readers' questions and pose them as a reader would.

- **Tables.** Tables make complex information readily understandable. They can help readers see relationships more easily, and they may require fewer words than straight text.

- **Typography.** Typography relates to fonts and typographical elements used for emphasis, such as bullets or italics. Limit the number of fonts you use. It is usually best to stick to one font for headings and another for text. Use typographical elements consistently throughout your document, and avoid overusing any one element.

4. Evaluate Your Document.

To ensure that you are communicating clearly, evaluate the document or, better yet, have another person read it and offer suggestions for clarification.

Look over the document for

- Word choice, verb forms, and structure
- Correct spelling, grammar, and punctuation
- Inclusion of appropriate devices, such as dates, page numbering, and consistency
- Visual appeal
- Consistency and effectiveness of layout
- Line breaks that inadvertently separate part of a name or date in a way that reduces clarity

Source: https://www.opm.gov/information-management/plain-language/

Plain Language Tips

Prefer Active Voice

In passive writing, the "doer" is hidden. Rather than say, "Somebody did something," we say, "Something was done by somebody," or we leave off the "by somebody" and just say, "Something was done." Passive writing can be ambiguous and clunky, but it may be a better choice when you don't know who did something, can't say who did something, or prefer to focus on what happened and not who did it. As a rule, use it less than 20% of the time and with intention.

Active

The manager asked all staff to submit draft accomplishment reports by COB Friday.

Passive

All staff were asked to submit draft accomplishment reports by COB Friday (by the manager).

Hallmarks of Passive Voice

- The "true" actor is either not in the sentence or is the object of a preposition. (Example: The ball was kicked by the boy.)
- The main verb cannot stand alone—it must always have a helping verb, regardless of tense.
- The main verb takes the form of the past participle, again regardless of tense. (Example: The ball is being kicked. The ball will be kicked. The ball had been kicked.)
- The subject of the sentence would be the direct object if you were to reconstruct it in active voice.

Try a Couple

1. The deadlines were met by the staff.

2. All time and attendance forms should be submitted by COB Friday.

Set Verbs Free

When a word ends in *tion, sion, ance, able, ence, ment, ness*, and *mant*, it is usually a "smothered verb"—that is, a verb that has been turned into a noun.

We did an **inspection** of the office.

VS.

We **inspected** the office.

This directive **is applicable** to all personnel who make use of voicemail.

VS.

This directive **applies** to all personnel who use voicemail.

Try a Couple

1. Use that form for the submission of your travel expenses.

2. The team held a meeting to give consideration to the plan.

Maintain Parallel Structure

Parallel structure means giving equal ideas equal grammatical structure. Notice the differences in these two:

The five phases of the interview are as follows:

- Introduction
- Establish Rapport
- Questioning for Information
- Summarizing for Accuracy
- Closing

The five phases of the interview are as follows:

- Introduce Self
- Establish Rapport
- Question for Information
- Summarize for Accuracy
- Close the Interview

A Few Rules to Help You

With two phrases or clauses, repeat the introductory word.

> Instead of: "It is far better to give than receive." Use: "It is far better to give than to receive."

With three phrases or clauses, repeat the introductory word or use it only with the first phrase or clause.

> Use: "We travel by sea, air, and car." Or: "We travel by sea, by air, and by car." But not: "We travel by air, by sea, and car."

With lists, ensure parallel structure.

> Instead of: “The coach told the players **that they should get** a lot of sleep, **that they should not eat** too much, and **to do** some warm-up exercises before the game.”

Use: "The coach told the players that they should **get** a lot of sleep, not **eat** too much, and **do** some warm-up exercises before the game."

Try a Few

1. The employee expected that he would present his project plan at the meeting, that he would have time to show his slide presentation, and that questions would be asked by attendees.

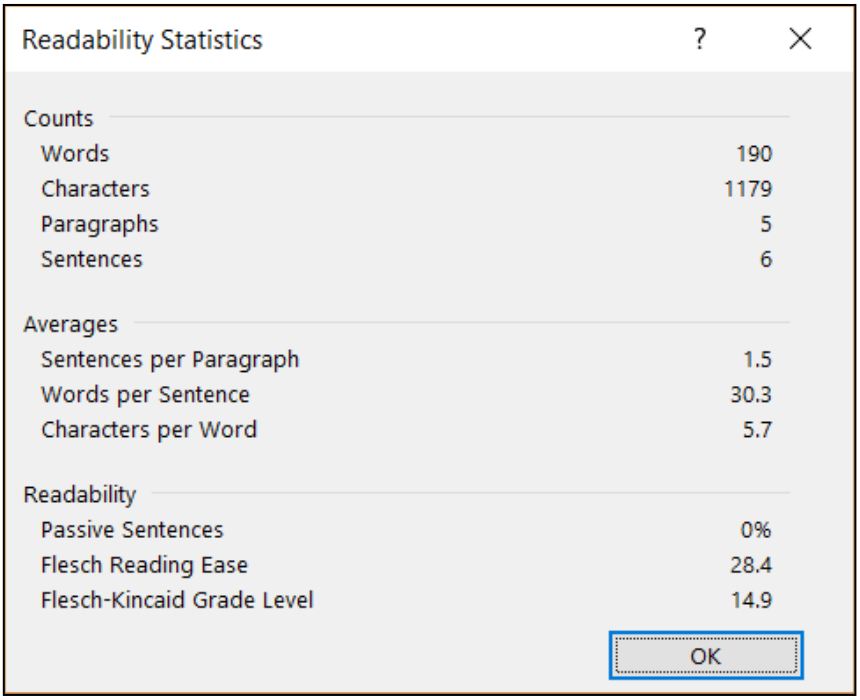
2. Staff are to safeguard the security of tissue specimens during preparation, storing, packaging, and submission of specimens for pathological or diagnostic microbiological evaluation.

3. We are seeking the following outcomes:
    - Collaboration with organizations in the community
    - Increase attendance at community meetings
    - Partner with other Federal agencies to host half-day quarterly informational sessions

Use the MS Word Proofing Tools

If you work in MS Word and Outlook, consider using the proofing tools to evaluate how well you are applying Plain Language principles. You can activate these tools easily using the instructions for both Word and Outlook that follow on page 4. Depending upon which version you are currently using, the steps may vary slightly.

When you review your document and have processed all the feedback on grammar, spelling, and usage, both Word and Outlook will give a synopsis of the readability of your writing in a dialogue box, like this:



Notice that the information includes these important details:

- Average words per sentence
- Average characters per word
- Percent of passive voice sentences
- Flesch Reading Ease Score
- Flesch-Kincaid Grade Level Score

While the primary criteria for readability are average sentence and word length, you will also want to pay attention to the percentage of passive voice, which also impacts reader understanding.

Ideal Numbers

So what are ideal numbers? It depends on the topic, audience, and document complexity. Some writing samples will have lengthy but unavoidable words, for example *Listeria monocytogenes*, and some documents will be extremely long. However, these recommended averages can help you evaluate and modify your writing.

Average Words per Sentence (15-20)

This is perhaps the most critical element of making writing digestible. Long sentences thwart understanding, so seek an average sentence length of 15-20 words.

Average Characters per Word (6)

The average word length in English is estimated to be six characters, so seek to maintain an average of six characters per word or less.

Percent of Passive Voice (Less than 20%)

As a rule, allow no more than 20% of passive voice sentences in your writing and generally seek a much lower number. We will discuss in more detail why active voice is a stronger expression and the circumstances when passive voice may be the better choice.

Flesch Reading Ease Score (RES of 40-70)

This test rates text on a 100-point scale. The higher the score, the easier it is to understand the document. A good goal is to aim for a score of 60-70. This can be difficult to attain, so minimally seek to have a score above 40.

Flesch-Kincaid Grade Level Score (GLS under 14)

This score indicates the number of years of formal education a reader would need to understand the writing sample. Traditionally, newspapers have attempted to write on the 8th grade level. However, for most government writing, a score of 8 can be hard to attain. Try to keep your score below 14.

Important Note: The more complicated the topic, the simpler the writing needs to be. Using shorter sentences, shorter words, and predominantly active voice will simplify your writing, even when relating complex information.

Activate Proofing Features in Outlook and Word

Outlook

1. Click **File**, and then click **Options**.
2. Click **Mail**, and then, under **Compose Messages**, click **Spelling and AutoCorrect.**
3. Click **Proofing**.
4. Under **When correcting spelling in Outlook,** select **Check grammar with spelling.**
5. Select **Show readability statistics**.

After you enable this feature, open a message that you want to review. When Outlook finishes checking the spelling and grammar, it displays information about the reading level of the document.

Word

1. Click the **File** tab, and then click **Options**.
2. Click **Proofing**.
3. Under **When correcting spelling and grammar in Word**, select **Check grammar with spelling.**
4. Select **Show readability statistics**.

Important: You have to correct or ignore all spelling errors found in the document before the readability statistics will display. If there are still any red squiggles in the file, the readability statistics won't display.

(Source, in part, from Office.com support page)

Important Points about Paragraphs

1. The first paragraph in a document sums up the message and acts as a road map for the rest of the letter or analysis. This "summing up" should give the result, outcome, or recommendation.

   This letter serves as official notice by the Food Safety and Inspection Service (FSIS) of the intent to withhold the marks of inspection and suspend the assignment of inspection program personnel for your Raw Non-Intact and Raw Intact Hazard Analysis Critical Control Point (HACCP) processes at BERGER COLI & Co., Inc., Establishment 01234 M/ P-01234. We are basing this action on our determination that your establishment's HACCP system is inadequate in accordance with Title 9 of the Code of Federal Regulations (CFR) part 417.6 (d), which states that a HACCP system may be found inadequate if the establishment is not adequately maintaining records. This letter provides background information on FSIS, explains our findings and basis for action, and gives you information on what steps you may take in response to this letter.

2. Each paragraph should have a topic sentence (or topic sentences) establishing a subject, a purpose, and an order.

   While statutory regulations require an establishment to have a pest management program to prevent the harborage and breeding of pests on grounds and facilities, your establishment did not do so. In reviews at your establishment from May through October 2008, FSIS inspectors noted the following infestations and accompanying NRs.

3. Each paragraph should contain information relevant only to the topic sentence (and the topic itself). Notice in the sample below how the underlined sentence dramatically changes the meaning and focus of this paragraph.

   Copies of the Acts are enclosed for your review. Please note that under section 23 (a) of the FMIA, and section 15 of the PPIA, the Secretary is authorized to exempt from inspection requirements the custom slaughter of livestock and the custom preparation of carcasses, and retail store poultry slaughter and processing operations. The exemption at any establishment shall be in effect for so long as the establishment maintains and operates its facility in a sanitary manner and complies with other requirements set forth in the Acts and regulations. Based on reports filed with this office, it has been determined that you have been unable or unwilling to comply with these provisions.

4. Most paragraphs have three to five sentences, but this can vary.

Exercise: Evaluate a Paragraph

Read and evaluate this paragraph.

The following information is provided to support this Notice of Intended Enforcement (NOIE) at your facility, which is based on repetitive positive findings of *Listeria monocytogenes* on product contact surfaces and intact product samples documented through two separate sampling protocols conducted by FSIS on DATE AND DATE, respectively. Also, the implementation of your established *Listeria* species sampling program has been shown to be ineffective in identifying potential harborages of this pathogen within your processing environment.

Organizational Styles

As a rule, write your EIAO documentation in the inverted pyramid (deductive) or the hourglass styles.

The Inverted Pyramid (Deductive)

The document or letter starts with the purpose in the first paragraph, with all remaining paragraphs supporting this main idea.

The Hourglass (Deductive with Repetition at the End)

The document, letter, or email begins and flows in the same way as the deductive approach, but the final paragraph reiterates the main idea. This is an excellent approach to use with requests. The format is “what I need or want, why and other details, and what I need or want again.” For a letter of NOIE, for example, the letter would begin and end with the intended action FSIS plans to take.

The Pyramid (Inductive)

The document or letter is written as a narrative argument or chronology that ends with a summation.

Example: *Starting on this date, we inspected your establishment and found evidence of rodent infestation. On this date, we wrote you… On this date, you responded… Therefore, we believe you may have violated FMIA…”*

Exercise: Determining Organizational Style

Determine the style for each paragraph.

Paragraph 1

Seven personnel were listed as having completed training in humane handling requirements. Documents indicated that these personnel had received per diem reimbursement for attending the training session. Documents also revealed the personnel did not attend the humane handling training. Therefore, these seven personnel were incorrectly paid per diem reimbursement for training they did not attend.

Paragraph 2

Seven personnel were incorrectly paid per diem reimbursement for training they did not attend. According to the documents we reviewed, these personnel were erroneously listed as having attended humane handling training and were then paid per diem reimbursement for travel they did not take.

Notes on “Person,” Abbreviations, Bullets, and Microbial Names

Referring to Yourself in FSA Documentation

You may refer to yourself in the third person or the first person: “EIAO Smith noted that…” or “I noted that…” in all entries except the Executive Summary. Generally, the Executive Summary will not include references to individuals, but if required, use the third person rather than the first person.

Consider using bulleted lists to avoid redundantly using “I,” “EIAO Smith,” or passive voice. For example, if you want to share a series of observations, start with an introduction, such as “I” (or EIAO Smith) noted the following” and then proceed with the list of observations as individual bullets (dust and debris on the slicing equipment, overflowing trash bins, and so on).

Using Bullets to Break Up Text

When you can break up long narrative passages with bullets, opt to do so. Ensure the bulleted items are like items, not merely a series of sentences placed behind a bullet. For example, the bulleted list might be a series of observations, a series of violations, and so on.

Your response should at a minimum include written sanitation procedures and pest control measures you have developed and implemented for your business operation on a daily and ongoing basis, including all written records completed on a daily basis, employee training, and other food safety measures to ensure your establishment meets statutory and regulatory requirements.

VS.

Your response should, at a minimum, include the following:

- *Written sanitation procedures and pest control measures you have developed and implemented for your business operation on a daily and ongoing basis*
- *All written records completed on a daily basis*
- *Employee training*
- *Any other food safety measures to ensure your establishment meets statutory and regulatory requirements*

Punctuating Bulleted and Numbered Lists

The guiding principle for using bulleted and numbered lists is to present information so it is quickly and easily understood. In the absence of prescribed style rules, consider using the following guidance:

- Use a period after every bullet point that is a sentence (as in this example).
- Avoid ending bullets with semicolons unless your in-house style dictates it.
- Ensure each item is a complete thought or a fragment—but not a mix of both.
- Prefer bullets when information is interchangeable and prefer numbering when the list indicates priority or order.
- Usually start each bullet with a capital letter.
- **Most importantly, in all matters, be consistent.**

Using Possessive and Plural Abbreviations

Ensure you are using the correct punctuation to convey that an abbreviation is singular, plural, and/or possessive. Adding an apostrophe and then "s" to an abbreviation conveys possession, as in "FSIS's policy." Adding an "s" and then an apostrophe conveys plural possession, as in "CSIs' meeting." Simply adding an "s" makes the abbreviation plural, as in SRMs.

- EIAO is singular (talking about a single EIAO).
- EIAOs is plural (talking about several EIAOs).
- EIAO's is the singular possessive form (one EIAO owns something, such as an EIAO's report).
- EIAOs' is the plural, possessive form (EIAOs' reports).

NOTE: Don't use an abbreviation without first spelling it out and adding the abbreviation in parentheses. Don't place the abbreviation in parentheses unless there will be a second reference. For analyses or summaries, assume the reader may not have read other parts of the document and may not know or have seen the abbreviation or acronym.

Using Correct Bacterial/Microbial Genus and Species Names

Italicize bacterial and microbial genus and species names, as in *Escherichia coli*. When abbreviating, capitalize the genus name and shorten it with a period after the first letter; keep the species name lowercase but do not abbreviate it, as in *E. coli*. Note that one common exception is *Listeria monocytogenes*, which is abbreviated *Lm.* Serotype is never italicized, but it is capitalized, as in *Salmonella* Hadar. Note that in *E. coli* O157:H7 what precedes the 157 is the letter O, not the number zero.

Here are some commonly used genus/species names:

- *Listeria monocytogenes or Lm*
- *Escherichia coli* or *E. coli*
- *Salmonella*
- *Salmonella* Enteritidis or *S.* Enteritidis
- *Salmonella* Hadar or *S.* Hadar
- *Salmonella* Typhimurium or *S.* Typhimurium
- *Campylobacter*
- *Campylobacter jejuni* or *C. jejuni*
- Shiga toxin-producing *E. coli or* STEC

Using Numbers and Dates

For FSAs

- Use numerals throughout (1, 9, 11, 20).
- Don’t repeat numbers in parentheses—five (5).
- Use abbreviated dates if you prefer (12/15/21) but be consistent.

Guidance for Other Writing Forms

- Write out zero to nine; use numerals for 10 and higher.
- Write out any number at the start of a sentence.
- Use numerals when referring to time or measurements: 24 months, 6 weeks, 3 days, 4 feet.
- With ranges above and below 10 in a single sentence, use numerals in all cases.
- Use one date format throughout a document.

Writing the PHRE Recommendation

You will document your rationale for, or against, conducting an FSA in PHIS using the PHRE Tool.

As specified in Directive 5100.4, review the PHRE Report to look for patterns, trends, or specific issues that should be investigated. Additionally, seek out and review lab results, consumer complaints, details of previous FSAs, any relevant enforcement reports, PFGE results for *Lm*-positive results, and feedback from the FLS and IPP on the report and the establishment's operating practices.

Next, make one of three recommendations and document that recommendation using the PHRE Tool:

1. Conduct an FSA.

   A recommendation to conduct an FSA leads to PHRE4, which prompts you to complete the assessment plan. The following pages have information on what to include in this plan and some sample assessment plans.

2. Do not conduct an FSA but take enforcement action.

   If you recommend an enforcement action, no FSA is needed.

3. Do not conduct an FSA.

   If you recommend against conducting an FSA, you will write the rationale in PHRE3. Guidance on writing this rationale and some sample responses follow below.

NOTE: The PHRE is an internal document and therefore is not to be distributed to the establishment. During the entrance meeting, the EIAO is to explain the reason for the FSA and answer questions about the overall process.

Completing the PHRE: The FSA Assessment Plan

When an FSA is recommended, you will create an Assessment Plan to ensure the assessment is thorough, well organized, and efficiently uses limited resources. The Assessment Plan should include the following elements:

1. Apparent Violations of the Statutes

   Briefly state the apparent or possible food safety issue(s) determined through the analysis. The plan is to cite the relevant statutes or regulations and state or paraphrase the language of the statutes or regulations—for example, “21 U.S.C. 453 (g)(4) and 458 (a)(3), improperly stored poultry products, after transportation in commerce, under insanitary conditions, causing the products to become adulterated.”

2. Scope of the FSA

   Briefly state the extent and range of the FSA, such as tools that will initially be used, regulatory issues, food safety issues or other matters, and any possible public health issues or concerns.

3. Steps of the Assessment

   List the steps necessary to develop facts and findings and to collect evidence of the apparent or possible food safety issues.

It is important to note that the assessment plan is meant to be a tool that illustrates the primary concern or concerns at the establishment that need to be investigated and why, along with a brief description of the approach for conducting the FSA. It is also an opportunity to seek out additional guidance or expertise. Unless necessary, the plan should not be lengthy, nor should it point out each of the customary steps involved. Rather, think of this plan as an overview of why the FSA is important to complete and what unique steps (and guidance) will be needed for this specific FSA.

If during the FSA new information causes the approach to change, the plan does not need to be updated as long as this new information is captured in the FSA itself.

Example of an FSA Assessment Plan (PHRE4)

The EIAO is recommending an FSA because the establishment had a Class I recall associated with a product containing an undeclared allergen. Since the establishment shipped product into commerce with an undeclared allergen, its food safety system failed. During the assessment, the EIAO's primary focus will be on the establishment's written allergen control procedures and implementation of any procedures to determine compliance with 9 CFR 417.2(a)(1) and 417.5(a)(1).

Because allergens may affect all products produced within the facility, the EIAO plans to complete all parts of each processing FSA tool except the Canning Tool. If during the assessment, the EIAO determines that certain tools do not apply, he will explain this change in the overall analysis section of the report.

The noncompliance report data indicate the establishment is 16.67% percent noncompliant for meeting general labeling requirements. The EIAO's scope of labeling will focus on ingredient statements to verify if final product labels include all non-meat/poultry ingredients, specifically to include allergens. Based on the large number of products produced at the establishment, it will not be possible to review all labels within the 5-7 days allowed. Because of this, the EIAO's primary focus will be on reviewing the establishment's decisions related to allergens in the hazard analyses, on associated prerequisite programs including supporting documentation, and on observations made in processing and storage areas. Due to the recall and the information documented in the MOIs and NRs, the establishment's ability to meet the requirements of FMIA 21 USC 601 (n)(1) is a focus of the assessment. As part of the assessment, the EIAO will review the establishment's corrective action and reassessment records associated with the undeclared allergen recall.

The establishment produces post-lethality exposed RTE product under Alternative 3 and the last R*Lm* conducted was in 2011. The MOIs and NRs indicate some issues with the establishment meeting SPS Requirements, including construction, ventilation/condensation, and sanitary operations. The EIAO will conduct an R*Lm* and pay special attention to the establishment's sanitation procedures and *Listeria* sampling and testing procedures to check compliance with 9 CFR 430, 417.5(a)(1) and 416. The EIAO will also review food safety decisions and corresponding supporting documents related to the production of post-lethality exposed RTE products.

The establishment's enforcement history includes an NOIE issued on September 13, 2011, for producing adulterated product as defined by the FMIA in 21 USC 601(m)(4). The establishment did not meet the requirements of 9 CFR 416.2(d), 416.13(b), 416.16(a), 417.2(a)(1)(2)(3), 417.2(b)(1), 417.2(c)(1) – (7), 417.4(a)(2), 417.5, and 430, resulting in an inadequate food safety system, as described in 9 CFR 417.6(a), (b) and (d). As part of the FSA, the EIAO will be verifying compliance with all the regulatory requirements.

Completing the PHRE:
Writing the Rationale for Not Initiating an FSA

When you determine that an FSA is not currently needed and select "no," you will then need to complete the PHRE3 question with your rationale for this decision. While the reasons for not initiating an FSA will vary, the basic structure for the rationale will include a statement indicating the FSA is not recommended and then the reasons for this, drawing upon information from the PHRE Report and the EIAO's review of lab results, consumer complaints, enforcement reports, PFGE results, and communication with the relevant FLS and IPP.

Here is an example of a well-written response to PHRE3:

The EIAO determined that an FSA is not needed at this time because a review of the findings in the PHRE Report does not show trends that a public health risk exists. The EIAO reviewed the PHRE Report and identified no public health related noncompliance records, no positive sample results, and no recalls at the establishment since the time of the last FSA, performed from 5/18 to 6/10/2013. Review of the Consumer Complaint Monitoring System (CCMS) shows there are no consumer complaints for this establishment.

The establishment produces pork rinds and pork cracklings under the Heat-Treated Shelf Stable HACCP category. No raw product enters the establishment. The source materials are purchased heat treated shelf stable. The establishment deep fries the pork rinds and crackling pellets. The frying process dries the product to a final water activity of ≤.20. The low water activity of the product will not support the growth of *Listeria monocytogenes* and it will not support the growth or germination of *Clostridium perfringens* spores. Challenge studies conducted at the University of Simpsonia on the products the establishment produces support a 1 to 2-log reduction of *Listeria monocytogenes* after one week of storage and a 3 to 4-log reduction after 5 weeks of storage. The establishment chose to produce the RTE pork rinds and pork cracklings under Alternative 3, sanitation measures only; however, with the low water activity of the finished product, Alternative 2 would be supported. The establishment has not had any Lm positive samples.

The EIAO spoke with FLS Dr. Julius Hibbert, who revealed no concerns. Dr. Hibbert met with the IIC at the establishment who also had no concerns. There have been few changes in operations over the past 15 years. Based on the PHRE report, previous FSAs, sampling results, and the conversation with the FLS there is no need for an FSA at this time.

Another Example of a Rationale for Not Initiating an FSA (PHRE3)

The EIAO is recommending that an FSA not be completed at Patriotic Foods, Inc. An assessment of the PHIS PHRE data, previous FSAs, and a discussion with in-plant inspection personnel indicates that the establishment has provided a sanitary environment, designed an adequate food safety system, and is implementing its SSOPs and HACCP plans as designed.

Patriotic Foods is a small establishment that further processes beef, swine, lamb, turkey, and chicken, utilizing raw intact and raw non-intact processing categories. Products include ground and fabricated pork products; tenderized beef products; and fabricated beef, veal, lamb, chicken, and turkey products.

The establishment has had no consumer complaints, enforcement actions, or recalls over the past 12 months.

An analysis of the noncompliance records over the past 6 months revealed 2 NRs, one for insanitary condition of nonfood contact surfaces during preoperational inspection and the other for an employee wearing a frock outdoors.

During the previous 5 years, a comprehensive FSA was conducted on 10/13/11 to satisfy the 4-year assessment cycle (Note: This was a previous requirement.).

The FSA resulted in a recommendation that the in-plant inspection personnel write 2 NRs for HACCP-design issues. A review of the 10/13/11 FSA and a discussion with FLS Dr. Ned Flanders and IIC Edna Krabappel indicated that the establishment utilizes and maintains adequate support for product temperature CCPs to control *E. coli* O157:H7, *Salmonella*, and *Campylobacter.* Additionally, the prerequisite programs are designed and implemented to support decisions in the hazard analysis that hazards are not reasonably likely to occur.

The prerequisite programs include an allergen control program, temperature monitoring systems at product receiving and storage and during processing, a BSE policy, product staging and receiving procedures, a returned-product policy, and a Sanova system to apply acidified sodium chlorite to beef prior to needle tenderization. The establishment has purchase specifications for beef that require its suppliers to have at least one validated intervention at slaughter and to test carcasses for *E. coli* O157:H7. In addition, the establishment adequately maintains and implements its SSOP, which includes ATP testing and visual inspection for metal contamination.

For all of these reasons, an FSA is not recommended at this time.

Exercise: Evaluating a PHRE3 Response

Analyze the following response. What is effective? What changes would you recommend? Compare this to the two suggested rewrites that follow.

A PHRE evaluation was completed on July 16, 2015, by EIAO Lisa Simpson using the methodology as described in FSIS Directive 5100.4 Rev. 1. Prior FSA reports were reviewed including the most recent performed in June of 2011 that included FSIS R*Lm* sampling with no unacceptable sampling results, thus there were no PFGE results to request. There was no available enforcement data or reports for the previous 12 months. Establishment regulatory compliance history including PHIS NRs for the previous 6 months was reviewed. Two NRs were issued in the past 3 months. The first documented a ventilation/condensation issue in a non-production area. No corrective actions were available for review in PHIS, but there was no reoccurrence. The second NR documented insanitary conditions of two food contact surfaces during the Pre-Operational Verification Tasks. Corrective actions were reviewed in PHIS and met 9 CFR 416.15. There were no associated NRs identified. PHIS profile data was reviewed. Weekly Meeting/IPP MOIs for the previous 6 months were reviewed and there were no food safety concerns identified. The establishment has not conducted a product recall within the last 12 months. FSIS conducts RTE product sampling at the establishment and there have been no unacceptable results within the last 6 months, thus there were no PFGE results to request. There was one CCMS-II consumer complaint within the last 6 months (06/08/2015) of a consumer reporting a hair found on a meat/cheese stick, OPHS conducted a search for similar cases apparently finding none and the case was closed out. The evaluation of establishment historical data and background information resulted in a determination that there were no food safety concerns identified. This, along with a telephone conversation with FLS Aristotle Amadopolis, DVM, as well as follow-up email communication between the EIAO and IIC Gary Chalmers resulted in a determination that there were no food safety concerns or continuing trends of regulatory noncompliance identified and the establishment is implementing adequate corrective actions/preventive measures in response to the recent NRs issued by FSIS and a FSA as result of the PHRE performed is not warranted at this time as the establishment is operating acceptably at this time.

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Exercise: Evaluating a PHRE3 Response with Instructor's Comments

A PHRE evaluation was completed on July 16, 2015, by EIAO Lisa Simpson **(1)** using the methodology as described in FSIS Directive 5100.4 Rev. 1. **(2)** Prior FSA reports were reviewed including the most recent performed in June of 2011 that included FSIS R*Lm* sampling with no unacceptable sampling results, thus there were no PFGE results to request. There was **(3)** no available enforcement data or reports for the previous 12 months. Establishment regulatory compliance history including PHIS NRs for the previous 6 months was reviewed. Two NRs were issued in the past 3 months. The first documented a ventilation/condensation issue in a non-production area. No corrective actions were available for review in PHIS, but there was no reoccurrence. The second NR documented insanitary conditions of two food contact surfaces during the Pre-Operational Verification Tasks. Corrective actions were reviewed in PHIS and met 9 CFR 416.15. There were no associated NRs identified. **(4)** PHIS profile data was reviewed. Weekly Meeting/IPP MOIs for the previous 6 months were reviewed and there were no food safety concerns identified. The establishment has not conducted a product recall within the last 12 months. FSIS conducts RTE product sampling at the establishment and there have been no unacceptable results within the last 6 months, thus there were no PFGE results to request. There was one CCMS-II consumer complaint within the last 6 months (06/08/2015) of a consumer reporting a hair found on a meat/cheese stick,**(5)** OPHS conducted a search for similar cases apparently finding none and the case was closed out. **(6)** The evaluation of establishment historical data and background information resulted in a determination that there were no food safety concerns identified. **(7)** This, along with a telephone conversation with FLS Aristotle Amadopolis, DVM, as well as follow-up email communication between the EIAO and IIC Gary Chalmers resulted in a determination that there were no food safety concerns or continuing trends of regulatory noncompliance identified and the establishment is implementing adequate corrective actions/preventive measures in response to recent NRs issued by FSIS and a FSA as result of the PHRE performed is not warranted at this time as the establishment is operating acceptably at this time. **(8)**

Instructor's Comments

1. There is no need to state that you are following the directive. This is assumed.
2. The answer (NO) is not presented until the end. While this is understood because the "NO" box is checked, it is still helpful to put the answer early and use the deductive writing approach.
3. This one could be negotiable because people often use data in the singular sense, but the verb should be "were" because data and reports are both plural.
4. The statement that "PHIS profile data was reviewed" is somewhat incomplete. The reader is left wondering, "And so what?" This would be a good opportunity to check for and confirm that the correct FSIS sample tasks or inspection tasks are being performed based on operations at the plant.
5. This sentence should be ended after "stick," and commas are needed around "apparently finding none."
6. This sentence is more difficult to understand than the others are because it has two "sions" and a passive verb.
7. This last sentence is too long and needs to be broken up into two or three sentences.
8. Overall, this writer packed a lot of information into a short writing sample. Though the sample has quite a bit of passive voice, many of these sentences are OK because we know who the actor is (the EIAO) and the thing we are most interested in is the RESULT of the reviews, not in who did the reviews. Nonetheless, this response could benefit from a higher percentage of active voice.

Version 1: Suggested Rewrite of PHRE3 Exercise

EIAO Lisa Simpson completed a PHRE evaluation on July 16, 2015, and determined that an FSA is not currently needed. As part of the evaluation, EIAO Simpson reviewed previously completed FSA reports and other relevant documentation. The most recent FSA, completed in June 2011, included FSIS R*Lm* sampling with no unacceptable sampling results, and thus there were no PFGE results to request.

The establishment had no enforcement data or reports for the previous 12 months. EIAO Simpson reviewed the establishment's regulatory compliance history, including PHIS NRs for the previous 6 months, finding two NRs, but no associated NRs. Of the two identified NRs, the first documented a ventilation/condensation issue in a non-production area. No corrective actions were available for review in PHIS, but there was no reoccurrence. The second NR documented insanitary conditions of two food contact surfaces during the Pre-Operational Verification Tasks. Corrective actions were reviewed in PHIS and met 9 CFR 416.15.

A review of the weekly meeting/IPP MOIs for the previous 6 months identified no food safety concerns. The establishment has not conducted a product recall within the last 12 months. FSIS conducts RTE product sampling at the establishment and there have been no unacceptable results within the last 6 months; thus, there were no PFGE results to request.

One CCMS-II consumer complaint was made on 06/08/2015, with a consumer reporting a hair found on a meat/cheese stick. OPHS conducted a search for similar cases, revealed no cases, and the case was closed out. A review of establishment historical data and background information did not identify any food safety concerns.

In communication with EIAO Simpson, neither FLS Aristotle Amadopolis, DVM, nor IIC Gary Chalmers cited any food safety concerns or continuing trends of regulatory noncompliance. The establishment is implementing adequate corrective actions and preventive measures in response to recent NRs issued by FSIS, and an FSA is not warranted at this time.

Version 2: Suggested Rewrite of PHRE3 Exercise

A PHRE evaluation was completed on July 16, 2015, by EIAO Lisa Simpson. Based on this review, the EIAO determined an FSA is not needed at this time. This recommendation is based on reviews of the following:

- Prior FSA reports, including the most recent performed in June 2011 that included FSIS R*Lm* sampling with no unacceptable sampling results and thus no PFGE results to request.
- Available enforcement data or reports for the previous 12 months indicating no action taken.
- Establishment regulatory compliance history, including PHIS NRs for the previous 6 months, with no associated NRs.
- Two issued NRs. (The first documented a ventilation/condensation issue in a non-production area. No corrective actions were available for review in PHIS, but there was no reoccurrence. The second NR documented insanitary conditions of two food contact surfaces during the Pre-Operational Verification Tasks. Corrective actions were reviewed in PHIS and met 9 CFR 416.15.)
- PHIS profile data with no updates made.
- Weekly Meeting/IPP MOIs for the previous 6 months with no food safety concerns identified.
- No establishment recalls within the last 12 months.
- No unacceptable results from FSIS's RTE product sampling at the establishment in the last 6 months, thus no PFGE results to request.
- One CCMS-II consumer complaint within the last 6 months (06/08/2015) of a consumer reporting a hair found on a meat/cheese stick, which led to OPHS searching for similar cases, finding none, and closing out the case.
- Establishment historical data and background information indicating no food safety concerns identified.

Additionally, the EIAO spoke with FLS Aristotle Amadopolis, DVM, and IIC Gary Chalmers to determine if either had any food safety concerns. This communication yielded that the establishment is implementing adequate corrective actions and preventive measures in response to recent NRs issued by FSIS.

General EIAO Documentation Tips

Guidance on Writing the FSA from FSIS Directive 5100.1

- Focus on assessing and analyzing the establishment's food safety system as a whole, with an emphasis on documenting vulnerabilities and noncompliance. While noncompliance needs to be noted, this should be but one aspect of the overall, big-picture assessment.
- Discuss vulnerabilities, even when there are no instances of noncompliance.
- Generally, do not make positive editorial findings.
- At the end of each tool, summarize the findings that best support the FSA recommendation or any enforcement actions you recommend for the establishment's HACCP system.
- Use the decision-making analysis section of the General Tool to provide an analysis of the background, applicable sample results, and observations made throughout the FSA to support the recommendation. Ensure the recommendation is supported by FSIS statutory and regulatory requirements (i.e., the Acts and 9 CFR).
- Provide a summary of the analysis in the Executive Summary, a synopsis of the FSA that should be approximately nine sentences long.

General Guidance for Writing EIAO Documentation

- Write for people "outside the neighborhood."

- Generally, address the most egregious problems first and then discuss remaining issues.

- Clearly describe documents and facts. For example, if a section of the HACCP plan is involved, or a CCP is at issue, specify the name of the document so the reader understands what document or section is at issue. If product is involved, describe the product, the quantity, and its condition, if applicable.

- Associate dates with documents, observations, and issues. For example, if the record shows that the plant failed to reassess its HACCP plan as required, when documenting the facts that led to this conclusion, make sure you include the date of the most recent HACCP plan.

- Identify persons involved by name and title. Clarify whether they are FSIS employees or plant personnel.

- Relate the noncompliance to accurate regulatory citations (but not "recitations"). Remember that as part of due process, FSIS must provide plant officials with information that clearly defines the nature of the noncompliance and the related regulatory requirement.

- Think about the bottom-line message you are trying to convey before putting it on paper. Ask yourself these questions: What do I want to convey? What essential information and facts are most important to discuss?

- Avoid jargon and excessive wordiness.

- Consider the appearance of the document. Avoid long sentences and paragraphs. Put material and information in logical order and in a format that is "easy to the eye," for example by indenting text and using bullets. Proofread documents. Check grammar and punctuation.

Key Ideas for Responding to FSA Tool Questions

When responding to the FSA tool follow-up questions, the biggest challenges are specifically answering the question, ensuring proper scope, and clearly demonstrating the critical thinking and analysis associated with the response.

Answer the Question

When reading an FSA tool, the reader expects that the answer to a question will in fact answer the question. Therefore, when writing your response, be sure to answer the question directly and then provide the detail that supports the response—not the other way around. Forcing yourself to answer directly the question will ensure a deductive approach.

Maintain Proper Scope

Scope in this case means having the right level of detail to answer fully the question without adding too much or irrelevant information or leaving out contextual information.

Use Critical Thinking

When making an observation, it is important to relate that observation to the criterion, regulatory requirement, document, sample result, or record that makes it relevant and important.

Tips for Writing FSA Tool Question Responses

DO

- Support your decision in every response. This means you will explain your rationale by citing documentation, observations, sample results, and regulations.
- Review the questions in a tool before you start to avoid redundancy. This will allow you to plan where various information and observations will go.
- Describe fully what you have seen so that readers have a visual understanding, as appropriate.
- Lead with your main idea and be sure you have answered the question.
- Keep your focus on assessing and analyzing the establishment's food safety system.

DO NOT

- Copy and paste responses from one question into another question. Instead, refer the reader to fuller response. If possible, give a one or two sentence synopsis that answers the question and then refer the reader to the fuller response. Example: "The establishment's practice of XYZ creates a vulnerability… Please see M2 for a full description of this vulnerability."
- Quote long passages from the regulations. Instead, simply cite references. For example, you may write, "Per 9 CFR 416.13, this plant is required to monitor the implementation of Sanitation SOPs at least once a day. We reviewed the plant's monitoring records, including their clean-up, pre-operation, and operational sanitation reports, and observed that the plant is monitoring its operations every 48 hours."
- Use jargon and abbreviations that might confuse the reader. For example, instead of using the plant's "TC program," write out Temperature Control Program.
- Make positive editorial comments, but be sure to support fully a recommendation of no further action.

NOTE: PHIS limits the number of text characters allowed in the follow-up question boxes. In most instances, the preferred approach would be no more than 5-10 lines of brief narrative. Bullet points are allowed and encouraged where appropriate. Some situations—such as numerous findings at the plant or a unique process that requires a longer description—will merit a lengthier entry.

Exercise: Critique a Response to a Follow-Up Question

In your team, analyze this response from the General Meat Tool. Make note of at least three observations, use a flipchart page to create a good outline, and write a new first paragraph. Be prepared to share your work.

G14 *(Single Choice) Are there any conditions associated with the structure (Sanitation Performance Standards) that would hinder the establishment's ability to maintain sanitary conditions?*

☑ **Yes**

G15 *Describe the vulnerabilities and cite any noncompliance, and document your analysis on how the conditions impact food safety.*

The first day of the FSA, 9/8/2015, the establishment was not operating. CSI Jasper Beardly, HACCP Manager Kent Brockman, and I toured the facility carefully inspecting the structure for soundness. Brockman was highly helpful and made certain we had easy access to all parts of the establishment. The slaughter area was adequately maintained with a small amount of rust visible on the structure stationing plates on the ceiling. The packing room was found acceptable. The basement contains a vacuum packaging room which is used occasionally. Across one wall there were pallets stacked in a manner that made visibility limited. There were used boxes, gloves, and some food wrappers in one corner which had the appearance of a collection of trash. Kent Brockman stated that the area had not been used for several weeks. On 9/10/2015, this area was again toured. The area was not in use that day although the plant had run slaughter and packing operations in their usual production areas. Noncompliances were found and documented on NR 1-2015-9136 and the insanitary areas were rejected. In the first large storage room in the basement, west of the basement stairs, there were 6 freezer racks (not in use) with a heavy layer of dust on them. This dust was visible and when wiped showed it could be easily transferred. In the same room, a drain coming through the ceiling near the east wall had water dripping around the outside of it. A beam in the same vicinity was rusted and had water stains indicating a constant problem. In this area one ceiling panel was missing. In the vacuum pack room four ceiling panels had been taken down and were lying on an unused vacuum pack machine. A drain pipe running the length of the ceiling with rubber insulation was only partially covered with white plastic. The white plastic cover that was on had a heavy coat of dust on the top surface. Rust and dust stains were visible along seam joints on the glass board walls. Dust and cobwebs were on an exhaust fan shroud on the west wall. Dust, cobwebs, and rust were visible on a table along the north wall holding boxes of labels and bags. The noncompliances were shown to HACCP Supervisor Kent Brockman. Since these rooms were not in use and not scheduled to be used prior to the plant having an extended shut down, Kent Brockman said they would correct all the issues with extra cleaning accomplished in this area from 9/23/15 through 9/26/15 and that the area would not be used until the deficiencies were corrected. He also said the rust would be cleaned from the slaughter area. Each day of the FSA the production areas of the establishment in use were observed and the production rooms in use were well maintained and sound.

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Passive Voice in “Critique a Response to a Follow-Up Question”

The first day of the FSA, 9/8/2015, the establishment was not operating. CSI Jasper Beardly, HACCP Manager Kent Brockman, and I toured the facility carefully inspecting the structure for soundness. Brockman was highly helpful and made certain we had easy access to all parts of the establishment. The slaughter area was adequately maintained with a small amount of rust visible on the structure stationing plates on the ceiling. The packing room was found acceptable. The basement contains a vacuum packaging room *which* is used occasionally. Across one wall**,** there were pallets stacked in a manner that made visibility limited. There were used boxes, gloves, and some food wrappers in one corner *which* had the appearance of a collection of trash. Kent Brockman stated that the area had not been used for several weeks. On 9/10/2015, this area was again toured. The area was not in use that day although the plant had run slaughter and packing operations in their usual production areas (run-on). Noncompliances were found and documented on NR 1-2015-9136 and the insanitary areas were rejected. In the first large storage room in the basement, west of the basement stairs, there were 6 freezer racks (not in use) with a heavy layer of dust on them. This dust was visible and when wiped showed it could be easily transferred. In the same room, a drain coming through the ceiling near the east wall had water dripping around the outside of it. A beam in the same vicinity was rusted and had water stains indicating a constant problem. In this area one ceiling panel was missing. In the vacuum pack room**,** four ceiling panels had been taken down and were lying on an unused vacuum pack machine. A drain pipe running the length of the ceiling with rubber insulation was only partially covered with white plastic. The white plastic cover that was on had a heavy coat of dust on the top surface. Rust and dust stains were visible along seam joints on the glass board walls. Dust and cobwebs were on an exhaust fan shroud on the west wall. Dust, cobwebs, and rust were visible on a table along the north wall holding boxes of labels and bags. The noncompliances were shown to HACCP Supervisor Kent Brockman. Since these rooms were not in use and not scheduled to be used prior to the plant having an extended shut down, Kent Brockman said they would correct all the issues with extra cleaning accomplished in this area during 9/23/2015 through 9/26/2015 and that the area would not be used until the deficiencies were corrected. He also said the rust would be cleaned from the slaughter area. Each day of the FSA**,** the production areas of the establishment in use were observed and the production rooms in use were well maintained and sound.

Observations on "Critique a Response to a Follow-Up Question in the General Tool"

1. This response is confusing. It seems that the author feels the important production areas are sound. Yet, the author cites many observations of dirt, dust, leaks, trash, rust, and so on. Additionally, the response indicates that an NR was issued.

2. Generally, the emphasis should be on vulnerabilities and noncompliance—not on what is OK and sound. This response could be shortened significantly and be more on point by eliminating the positive commentary, including the positive comment about Brockman's helpfulness.

3. A rewrite should include a better topic sentence and organization, as well as some simple formatting. If all of the content is left in, it needs to be two or three paragraphs, and the observations should be presented as bulleted lists.

4. If the establishment made corrections to relevant findings during the FSA, this could be noted. Ideally, if the findings are relevant to the outcome of the FSA, for example enforcement, then it is best to indicate if the corrective actions will address the concern raised in the FSA. However, a blanket statement about every NR issued and whether the establishment has addressed corrective actions is not necessary. Items G12 and G13 allow the EIAO to indicate if an NR requires follow up.

   If the establishment has not made corrective actions before the end of the FSA, and if the NR is significant or complex, the 5100.1 directive allows for the EIAO to follow-up after the FSA is completed. In that case, the EIAO should mention it in the FSA tools questions. Additionally, when the noncompliance is part of a larger enforcement action, the NR may not actually be written at the time, but rather folded into the enforcement action recommended by the FSA.

5. The author has done a good job of describing what he saw, so the reader is easily able to envision the issues. However, the writing suffers from too much passive voice, and there are some shifts in tense.

6. Finally, the writing sample is missing several commas after introductory phrases and before "which" statements. (Alternately, "which" could be replaced with "that.")

Suggested Rewrite of "Critique a Response to a Follow-Up Question"

G14 *(Single Choice) Are there any conditions associated with the structure (Sanitation Performance Standards) that would hinder the establishment's ability to maintain sanitary conditions?*

☑ **Yes**

G15 *Describe the vulnerabilities and cite any noncompliance, and document your analysis on how the conditions impact food safety.*

On 9/8/2015 and 9/10/2015, I (or EIAO Blank) toured the facility with CSI Jasper Beardly and HACCP Manager Kent Brockman and identified multiple sanitation noncompliances in the vacuum packaging room and a large storage room in the basement area. The specific concerns are outlined below. Please note that the storage room is a nonproduction area, and the vacuum packaging room was not in use at the time but is used occasionally. The IPP rejected the insanitary areas and documented the noncompliance on NR 1-2015-9136. The establishment has scheduled complete cleaning of the areas the week of 9/23. I (or EIAO Blank) recommend the areas remain rejected until the establishment restores sanitary measures.

The specific concerns in the vacuum packaging room and the storage area were as follows:

Vacuum Packaging Room

- Across one wall, a stack of pallets limited visibility.
- Boxes, gloves, and some food wrappers in one corner appeared to be a pile of trash.
- Four ceiling panels had been removed and were lying on an unused vacuum pack machine.
- An approximate 6-foot portion of rubber insulation was missing on a 14-foot drainpipe. The portion of insulation that remained had a heavy coating of dust.
- Rust and dust stains were visible along seam joints on the glass board walls.
- Dust and cobwebs were visible on an exhaust fan shroud on the west wall.
- Dust, cobwebs, and rust were visible on a table along the north wall holding boxes of labels and bags.

Large Storage Room (located west of basement stairs)

- Six freezer racks, not in use, had a heavy layer of dust on them. This dust was visible and when wiped was transferred easily.
- A drain coming through the ceiling near the east wall had water dripping around the outside of it.
- A beam close to this same drain was rusted and had water stains indicating an active leak.
- A ceiling panel was missing.

Writing a Tool Summary

- Use the summary question at the end of each tool to focus on the most significant noncompliance(s) or vulnerabilities that can affect an establishment's ability to produce safe, wholesome, and unadulterated product.

- Present these findings as 3-5 bullet points.

- If a bulleted finding needs a narrative explanation, follow the bullet with an explanation.

- Write the summaries carefully and ensure they fully capture the critical findings.

- Use information from the tool summary (or summaries if more than one tool is completed) to write the Decision-Making Analysis and the Executive Summary.

- Be aware that this summary should capture the essence of the information collected using that tool. It should not be lengthy, nor should it be a chronology of the FSA.

- Do not reference other tool questions within the summary because the summary should be considered a stand-alone entry.

Example of a Tool Summary (NRTE Tool)

- The deviation from the critical limit on June 20, 2015, during the FSA showed that monitoring procedures performed at the filling step were vulnerable and may not be preventing pathogen growth and therefore may have an impact on the establishment's ability to produce safe, wholesome, unadulterated NRTE products for the consumer. The establishment failed to meet the requirements of 9 CFR 417.5(a)(2) and 417.2(c)(4), with documentation occurring at the time of the event by IPP on NR # XXXXX. Specifically,, the food preparation process results in the product being exposed to room temperatures for potentially extended periods. The EIAO requested that the establishment take a product temperature of the product that was staged on the racks. The product's temperature was 62°F, which was above the establishment's critical limit of ≤ 45°F.

- The EIAO is recommending that IPP issue an NR for regulatory non-compliance with the verification and recordkeeping requirements in 9 CFR 417.4(a)(2)(i)(ii)(iii) and 417.5(c). Even though the establishment conducted monitoring activities at the described frequency, the establishment failed to do the following: conduct verification activities to ensure the thermometers were functioning properly; verify process control with a direct observation of the monitoring procedures; review generated records; and conduct a pre-shipment review to ensure completeness for all products produced. Failure to complete these actions may create a vulnerability in the establishment's food safety system for their HTNFCNSS process. The failure to conduct verification activities does not ensure that the establishment is maintaining process control and could allow the production of misbranded or adulterated products.

- The establishment lacks validated cooking instructions for the items par fried after filling. Review of the FSIS product labels for the Yummy Bites product found that they state: "Heat oil to 350 degrees Fahrenheit and cook for 1 ½ to 2 minutes. Or until golden brown." Therefore, the establishment's lack of validated cooking instruction does not support the decisions made in the hazard analysis for the Yummy Snacks or support the cooking instructions printed on the label for NRTE products that have the appearance of being RTE. This is not compliant with the requirements of 9 CFR 417.5(a)(1) and could affect the establishment's ability to produce safe, wholesome, and unadulterated product for the consumer. The EIAO is recommending an NR be documented by IPP to address this noncompliance.

Exercise: Critique and Rewrite a Meat Tool Summary

Read, critique, and rewrite this Meat Tool Summary. Also, underline each passive voice construction.

Bouvier Fine Meats produces various intact and non-intact meat products. Some meat products are processed from boxed beef received and others are processed from carcasses received. The Hazard Analysis concluded that there are no pathogens, including *E. coli* O157:H7, reasonably likely to occur on received products. Pathogen growth was deemed likely to occur and a HACCP plan was created to ensure room temperatures were controlled to prevent outgrowth of pathogens.

The Hazard Analysis, HACCP plan and accompanying required documentation failed to meet regulatory requirements as set forth in 9 CFR 417 for the following issues.

Incoming intact boxed beef intended for needle tenderization and the carcasses intended for further processing into trim for grinding lack support for the decision made that *E. coli* O157:H7 is unlikely to occur at receiving. According to Bouvier Fine Meats, *E. coli* O157:H7 is unlikely to occur because supporting scientific articles supplied say there is an extremely low prevalence that exists and that products they receive are subjected to at least one validated intervention to reduce to an undetectable level pathogens of concern at the supplying plants as indicated in yearly Letters of Guarantee and third party audits. In the unlikely case that *E. coli* O157:H7 did contaminate a carcass or boxed beef intended for non-intact use, they have proposed (and initiated by the end of the FSA) a program that sprays carcasses with acidified sodium chlorite (ASC), using a hand sprayer. Boxed beef intended for tenderization is run through a spray cabinet. Both the carcass spray and spray cabinet utilize ASC to reduce *E. coli* O157:H7 to undetectable levels. The ASC is validated to reduce *E.coli* O157:H7 by 1 to 2 logs. The carcass spray is instituted, but there is no data at this time to verify the efficacy of the program. Trim created from the boxed beef is labeled “for cooking only” and is sent to establishments that cook it to lethality.

When conducting the Hazard Analysis, an establishment needs to consider food safety hazards that are reasonably likely to occur before, during, and after entry. In this case, Bouvier Fine Meats failed to support their decision that *E. coli* O157:H7 is unlikely to occur in received boxed beef and carcasses. Under HACCP regulations, the receiving establishment must perform on-going activities to verify that its HACCP plan is being effectively implemented and maintain documents that support those activities, and the frequency with which it performs them, are appropriate to accomplish their intended purpose.

Receiving a yearly LOG or third-party audit from suppliers does not constitute ongoing verification activities. There is no evidence provided of communication between Bouvier and its suppliers on an ongoing basis that demonstrates there are consistent and effective controls in place to ensure *E. coli* O157:H7 is not present at a detectable level in product being received at the establishment. According to 9 CFR 417.2 (a), "a food safety hazard that is reasonably likely to occur is one for which a prudent establishment establishes controls because it historically has occurred…." *E. coli* O157:H7 has been shown to occur in recent recalls, and human illness has been associated with ground beef and cuts intended for non-intact use (tenderized subprimals) from other establishments. This further indicates that reliance on scientific articles and yearly LOG from other establishments is not enough to conclude that incoming product has undetectable levels of *E. coli* O157:H7. *E. coli* O157:H7 is considered an adulterant in beef products intended for non-intact use. This includes subprimals that are tenderized.

The approved supplier program also calls for all beef products intended for grinding to be accompanied by a Certificate of Analysis (COA) indicating a negative test for *E. coli* 0157:H7 using an approved testing methodology. Incoming carcasses that are further fabricated have the trim ground. They are not received with COAs.

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Meat Tool Summary: Passive Voice Identified

Bouvier Fine Meats produces various intact and non-intact meat products. Some meat products are processed from boxed beef received and others are processed from carcasses received. The Hazard Analysis concluded that there are no pathogens, including *E. coli* O157:H7, reasonably likely to occur on received products. Pathogen growth was deemed likely to occur and a HACCP plan was created to ensure room temperatures were controlled to prevent outgrowth of pathogens.

The Hazard Analysis, HACCP plan and accompanying required documentation failed to meet regulatory requirements as set forth in 9 CFR 417 for the following issues.

Incoming intact boxed beef intended for needle tenderization and the carcasses intended for further processing into trim for grinding lack support for the decision made that *E. coli* O157:H7 is unlikely to occur at receiving. According to Bouvier Fine Meats, *E. coli* O157:H7 is unlikely to occur because supporting scientific articles supplied say there is an extremely low prevalence that exists and that products they receive are subjected to at least one validated intervention to reduce to an undetectable level pathogens of concern at the supplying plants as indicated in yearly Letters of Guarantee and third party audits. In the unlikely case that *E. coli* O157:H7 did contaminate a carcass or boxed beef intended for non-intact use, they have proposed (and initiated by the end of the FSA) a program that sprays carcasses with acidified sodium chlorite (ASC), using a hand sprayer. Boxed beef intended for tenderization is run through a spray cabinet. Both the carcass spray and spray cabinet utilize ASC to reduce *E. coli* O157:H7 to undetectable levels. The ASC is validated to reduce *E.coli* O157:H7 by 1 to 2 logs. The carcass spray is instituted, but there is no data at this time to verify the efficacy of the program. Trim created from the boxed beef is labeled “for cooking only” and is sent to establishments that cook it to lethality.

When conducting the Hazard Analysis, an establishment needs to consider food safety hazards that are reasonably likely to occur before, during, and after entry. In this case, Bouvier Fine Meats failed to support their decision that *E. coli* O157:H7 is unlikely to occur in received boxed beef and carcasses. Under HACCP regulations, the receiving establishment must perform on-going activities to verify that its HACCP plan is being effectively implemented and maintain documents that support those activities, and the frequency with which it performs them, are appropriate to accomplish their intended purpose.

Receiving a yearly LOG or third-party audit from suppliers does not constitute ongoing verification activities. There is no evidence provided of communication between Bouvier and its suppliers on an ongoing basis that demonstrates there are

consistent and effective controls in place to ensure *E. coli* O157:H7 is not present at a detectable level in product being received at the establishment. According to 9 CFR 417.2 (a), "a food safety hazard that is reasonably likely to occur is one for which a prudent establishment establishes controls because it historically has occurred…." *E. coli* O157:H7 has been shown to occur in recent recalls, and human illness has been associated with ground beef and cuts intended for non-intact use (tenderized subprimals) from other establishments. This further indicates that reliance on scientific articles and yearly LOG from other establishments is not enough to conclude that incoming product has undetectable levels of *E. coli* O157:H7. *E. coli* O157:H7 is considered an adulterant in beef products intended for non-intact use. This includes subprimals that are tenderized.

The approved supplier program also calls for all beef products intended for grinding to be accompanied by a Certificate of Analysis (COA) indicating a negative test for *E. coli* 0157:H7 using an approved testing methodology. Incoming carcasses that are further fabricated have the trim ground. They are not received with COAs.

Observations on “Critique and Rewrite Meat Tool Summary”

This is a good start. It is fairly well organized, and it clearly states that the establishment is noncompliant and is failing to meet regulatory requirements.

However, it has a few areas that need work. These include the following:

1. The last sentence in the first paragraph (*Pathogen growth was deemed likely to occur and a HACCP plan was created to ensure room temperatures were controlled to prevent outgrowth of pathogens*) does not add to the analysis and, in fact, distracts from the matter at hand.

2. The final paragraph about the COAs is vague. Does this mean they have never received COAs? This would need to be clarified and contain more specific information about how often and when, if ever, the establishment received COAs.

3. Two of the sentences are very long. Specifically, see the second sentence in the third paragraph, which is 64 words long. Additionally, look at the third sentence in the fourth paragraph, which is 42 words long.

4. This analysis is 50% passive voice, which “fogs up” the writing significantly.

Suggested Rewrite of Meat Tool Summary

The establishment cannot support the decision that *E. coli* O157:H7 is NRLTO in accordance with 9 CFR 417.5(a)(1) and 417.2(a)(1). Specific examples of Bouvier's inadequate support include the following:

- Scientific articles Bouvier provided said there is an extremely low prevalence of *E. coli* O157:H7. While establishments are commended for staying abreast of scientific research associated with food safety, these articles do not specifically correlate with the products produced by Bouvier and do not provide the necessary validation to support the decision that the pathogen is NRLTO.
- Bouvier proffered annual Letters of Guarantee (LOG) and third-party audits and stated that products they receive have had at least one validated intervention applied by the supplying establishments to reduce pathogens of concern to an undetectable level. However, annual LOG or third-party audits do not constitute ongoing communication between Bouvier and its suppliers on an ongoing basis that demonstrates consistent or effective controls to reduce *E. coli* O157:H7 to undetectable levels.
- Bouvier failed to follow the "Approved Supplier Program," which requires beef products intended for grinding to be accompanied by a Certificate of Analysis (COA) with negative test results *for E. coli* O157:H7 or to be held until tested for *E. coli* O157:H7. Bouvier neither receives COAs from their supplier nor performs tests for the pathogen.
- During the Food Safety Assessment (FSA), Bouvier proposed and initiated a program that sprays carcasses (using a hand sprayer) and boxed beef (in a spray cabinet) with acidified sodium chlorite (ASC). ASC is validated to reduce *E. coli* O157:H7 by 1 to 2 logs, and although Bouvier has implemented the ASC spray program, there is no data available to verify the efficacy of the program.

Writing the Decision-Making Analysis (DMA) in the General Tool

You will write your overall recommendation and the rationale for it in the decision-making analysis (DMA) section (G5) of the General Tool. The DMA is an especially important part of the FSA because it captures the recommendation and the support for this recommendation.

Within the DMA, you will include relevant findings and interpret these findings and their impact on the establishment's ability to produce safe, wholesome, and unadulterated product. In doing so, you will provide context and support for your recommendation.

- Write the DMA using the findings in the tool summaries, including the General Tool Summary (G54).
- Additionally, use the DMA to share information on relevant results from R*Lm*, IVT, or IIT sampling, PHRE, and in-plant observations.
- Note that the text box in PHIS allows for up to 20,000 characters; however, the ideal DMA will be one to two pages, far less than 20,000 characters.
- Consider the "puzzle pieces" before you begin writing the DMA. Review the tool summaries and any other content you feel is important, including sampling data, PHRE, observations, and so on.
- As appropriate, clearly identify what is noncompliance and what is a vulnerability.
- Be sure to lead with the recommendation(s) and an overview of the findings. If desired, give brief information about the facility and process.
- Consider using small headers to separate content. For example, if your DMA needs to address sampling, sanitation, and HACCP design—and if these can and should be addressed separately—use headers to guide the reader.
- If desired, use the "hourglass" structure and repeat the recommendation(s) at the end of the DMA.

- Create a simple outline to guide you as you begin. One approach does not work all of the time, so use critical thinking to help you.

    Example: are there two distinct and separate findings? If so, then lead with the recommendation and the fact that there are two findings. Then follow this initial paragraph with a paragraph on each of the findings and their impact on food safety.

    Example: is there a single finding of noncompliance and two potential vulnerabilities that are not violations? If so, state this in the opening paragraph (along with the recommendation, of course), and then follow with information on each of these three items.

    Example: is there a recommendation of no further action but NRs by in-plant personnel? State this in the first paragraph, give a very brief overview of the fact that the establishment is meeting regulatory requirements, and then expand on why each NR needs to be written.

Sample DMA in Outline

Recommendation in 1-2 sentences

EIAO Blank is recommending issuance of an NR by IPP because the establishment failed to conduct sampling at the location described in the written program for process control organisms at post-chill and failed to support the selection of *Enterobacteriaceae* as the indicator organism, leading to a failure to meet 9 CFR 381.65(g). Additionally, the establishment does not have a written recall procedure as required by 9 CFR 418.3.

Analysis and Explanation

Issuance of an NR for these noncompliances is appropriate because (*detail here on your thought process and the impact on the establishment's ability to produce safe, wholesome, and unadulterated product*)…

Additional Information on Reason for FSA and Other Relevant Findings

EIAO Blank conducted this FSA for cause at the request of the Frontline Supervisor and IPP. A review of the PHRE report indicates that the establishment maintains records as required, has not had an enforcement action in the past 12 months, has not conducted any product recall, and had no positive samples for *Salmonella*, *Campylobactor*, or residue in the past 12 months.

Reiterate Recommendation

In summary, the establishment has failed to design, implement, and maintain a sampling program to demonstrate process control and has not developed written recall procedures. Thus, EIAO Blank is recommending the issuance of NRs by IPP with a follow-up in 30 days by an EIAO to ensure that a scientifically supported sampling plan along with sample results for either the pathogens of concerns (*Salmonella* or *Campylobactor*) or an indicator organism are in place as required by the New Poultry Slaughter Inspection's final rules.

Exercise: Comparing a DMA "Before" and "After"

Read the DMA below and then read the DMA on pages 73-74. What changes do you notice? Please make note of at least three significant differences.

BEFORE

This FSA was conducted to evaluate the establishment's food safety system due to potential changes in the HACCP plans because of the recent change in ownership. All HACCP systems, SSOPs, recall program, and general food defense program were evaluated during the FSA. in addition to discussions with IIC Lenny Leonard. Montgomery Burn's Foods USA is a small establishment producing Raw Intact, Raw Non-Intact, and Fully Cooked – Not Shelf Stable products. Products include fabricated raw and RTE beef, pork, chicken, and turkey products. All RTE post lethality exposed products are produced under Alternative 3.

Review of the establishment's HACCP systems indicated that all hazards associated with the products produced and production processes were identified and addressed; providing measures for the prevention or control of potential hazards. The establishment identified product temperature during processing as a hazard RLTO in raw products and product cooking and stabilization temperatures as RLTO in RTE products; for which CCPs were developed. Management provided reliable supportable documentation for decisions made in the hazard analysis and in the development of CCPs. CCPs for monitoring raw product's temperatures during processing were supported by FDA's Food Code, Section: 3-5 Limitation of Growth of Organisms of Public Health; while RTE product's temperatures during cooking and stabilization were supported by FSIS's Appendix A: Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products.

The establishment is implementing controls as described in the support documents with the exception of not monitoring the oven's relative humidity during product cooking. An establishment relying on FSIS' Appendix A for cooking RTE products is required to meet all the parameters of the process schedule, including the relative humidity of the ovens. The time-temperature table in Appendix A is based on wet-heat. Without humidity, the product will dry, and the bacteria may become more heat resistant (Goepfert, 1970; Goodfellow and Brown, 1978; Faith, N.G. et al. 1998). Failure to achieve the required levels of pathogen lethality during the cooking process may allow for viable pathogens on products which may render then injurious to health. As described, the establishment failed to support the adequacy of the CCP in controlling the hazard (pathogen lethality during the cooking cycle). This failure to meet the requirements of 9 CFR Part 417.5(a)(2) for design of the HACCP system was documented on a NR issued by IPP during the FSA.

Reviews and observations of the implementation of the HACCP systems and associated records (prerequisite records, HACCP records, test results, FSIS's MOIs, and FSIS'sNR) demonstrated that management is implementing the HACCP plans as described. No noncompliances related to the implementation of the HACCP systems were identified by the EIAO; however, vulnerabilities associated with the food safety system were identified.

The establishment adds non-meat ingredients to raw products and to RTE products after the lethality step. Management addressed hazards associated with these upon receiving and during storage and determined that non-meat ingredients are a hazard NRLTO based on prerequisite programs for allergen control, suitability of ingredients, and manufacturer pathogen controls (COAs from manufacturer that these have been subject to pathogen controls, shelf stability, etc.). However, dry non-meat ingredients, such as spices and breadcrumbs, added to raw products and RTE products after the lethality step, are removed from their original containers and placed in bins for their dispensing and storage between uses. Even though ingredients are covered while stored in these bins, they are stored in a high humidity area (room is washed daily). These storage bins are not sealed; allowing for moisture to come in in contact with the ingredients. The establishment has not addressed the potential for changes in ingredient's moisture levels during long storage periods, which may allow for pathogen, mold, and / or yeast growth. During the FSA, the EIAO did not observe that ingredients had become contaminated or that these were stored under insanitary conditions that may cause products to become adulterated. No evidence of mold or yeast growth were observed in non-meat ingredients; however, there is a concern that if storage conditions are not monitored, insanitary conditions could develop causing product to become adulterated.

This establishment operates under dual jurisdiction (FSIS/FDA); however, management does not make any distinction between SSOP procedures for FSIS or FDA products. FSIS requirements are being following for all processes. Facilities, grounds, equipment, and utensils were observed to be well maintained preventing the creation of insanitary conditions that may adulterate product. SSOP procedures were observed to be implemented as described. The establishment is meeting the requirements of 9 CFR Parts 416.1-416.4 for facilities and equipment, as well as, Parts 416.11-416.16 for the development and implementation of SSIOPs.

Analysis/Recommendation:

The noncompliance identified during the assessment indicate a failure by the establishment to support the design of the HACCP plan, as required by 9 CFR Part 417.5(a)(2). Actual in-plant observation of monitoring activities support the absence of any immediate food safety concern, yet the establishment has a responsibility to support the adequacy of the design of their food safety system and maintain documentation to demonstrate the proper implementation and effectiveness of that design, as required by 9 CFR Part 417.5. There were no issues identified, including identified vulnerabilities associated with non-meat ingredient storage or product traceability, which demonstrate the creation of insanitary conditions which may render product adulterated.

The noncompliance was addressed on a NR issued by IPP during the FSA. Vulnerabilities identified were discussed by plant management. There were no issues of noncompliance creating an imminent threat to food safety that warranted a recommendation for an enforcement action in accordance with the Rules of Practice. The EIAO recommends that the FLS be contacted in 30 days or the EIAO visit the establishment to verify that the establishment has implemented actions to meet Part 417.4.

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AFTER

EIAO Blank's review of all HACCP systems, SSOPs, the recall program, and the general food defense program, as well as consultations with FSIS IIC Lenny Leonard, lead to a recommendation of no further enforcement action. However, during the FSA, IPP issued one NR related to the establishment's failure to monitor oven humidity, a violation of 9 CFR Part 417.5(a)(2). Additionally, the EIAO noted a vulnerability related to the storage of non-meat ingredients. Because of this NR and the noted vulnerability, the EIAO is recommending follow up within 30 days to confirm the establishment has implemented actions to meet Part 417.5. Follow-up can be through the FLS or through a visit from the EIAO.

This FSA was conducted to evaluate the establishment's food safety system due to potential changes in the HACCP plans because of a recent change in ownership. Montgomery Burn's Foods USA is a small establishment producing Raw Intact, Raw Non-Intact, and Fully Cooked Not Shelf Stable products. Products include fabricated raw and RTE beef, pork, chicken, and turkey products. All RTE post-lethality exposed products are produced under Alternative 3.

Review of the establishment's HACCP systems indicated that the establishment has identified and addressed all hazards associated with the products produced and its production processes. Except for the NR that was issued and the cited vulnerability, the EIAO noted that the establishment is implementing controls as described in the support documents. There were no additional issues of noncompliance creating an imminent threat to food safety that warranted recommending an enforcement action in accordance with the Rules of Practice.

Details on the NR and the cited vulnerability follow below.

NR #123456

> An NR was issued as a result of the establishment's failure to meet the requirements of 9 CFR Part 417.5(a)(2). Specifically, the establishment identified product temperature during processing as a hazard RLTO in raw products and product cooking and stabilization temperatures as RLTO in RTE product, for which CCPs were developed. Management provided reliable supportable documentation for decisions made in the hazard analysis and in the development of CCPs. The establishment is implementing controls as described in the support documents with the exception of not monitoring the oven's relative humidity during product cooking. An establishment relying on FSIS's Appendix A for cooking RTE products is required to meet all the parameters of the process schedule, including the relative humidity of the ovens. The time-temperature table in Appendix A is based on wet-heat.

Without humidity, the product will dry, and the bacteria may become more heat resistant (Goepfert, 1970; Goodfellow and Brown, 1978; Faith, N.G. et al. 1998). Failure to achieve the required levels of pathogen lethality during the cooking process may allow for viable pathogens on products, which may render them injurious to health. As described, the establishment failed to support the adequacy of the CCP in controlling the hazard (pathogen lethality during the cooking cycle).

Food Safety System Vulnerability

A vulnerability with the food safety system was also identified. The establishment adds non-meat ingredients to raw products and to RTE products after the lethality step. Management addressed hazards associated with these upon receiving and during storage and determined that non-meat ingredients are a hazard NRLTO based on prerequisite programs for allergen control, suitability of ingredients, and manufacturer pathogen controls (COAs from manufacturer that these have been subject to pathogen controls, shelf stability, etc.). However, dry non-meat ingredients, such as spices and breadcrumbs, added to raw products and RTE products after the lethality step, are removed from their original containers and placed in bins for their dispensing and storage between uses. Even though ingredients are covered while stored in these bins, they are stored in a high humidity area (room is washed daily). These storage bins are not sealed, allowing for moisture to come into contact with the ingredients. The establishment has not addressed the potential for changes in ingredients' moisture levels during long storage periods, which may allow for pathogen, mold, and/or yeast growth. During the FSA, the EIAO did not observe that ingredients had become contaminated or that these were stored under insanitary conditions that may cause products to become adulterated. No evidence of mold or yeast growth were observed in non-meat ingredients; however, there is a concern that if storage conditions are not monitored, insanitary conditions could develop causing product to become adulterated.

While the noncompliance identified during the assessment indicates a failure by the establishment to support the design of the HACCP plan, as required by 9 CFR Part 417.5(a)(2), actual in-plant observation of monitoring activities supports the absence of any immediate food safety concern at present. However, the establishment has a responsibility to support the adequacy of the design of their food safety system and maintain documents that demonstrate the proper implementation and effectiveness of that design, as required by 9 CFR Part 417.5.

Writing the Executive Summary

The executive summary, documented in the General Tool, should give readers a brief overview of the FSA's recommendations and support. You should write this after you have made a recommendation and completed the decision-making analysis. The executive summary should not exceed 350 words.

The purpose of the executive summary is to lay out concisely the principal findings of the FSA report in relation to the focus and execution of the assessment plan developed under FSIS Directive 5100.4. After reading the executive summary, the reader should understand the main regulatory findings that support any conclusion(s) that the establishment is not meeting specific sections of the Acts.

A good executive summary contains the following:

1. A sentence or two that describes the establishment and its processes, including the major types of products it produces

2. A sentence or two that describes the establishment's compliance history

3. A sentence that describes the sampling results, if applicable

4. A couple of sentences that describe the major findings leading to the recommendation

5. A couple of sentences that discuss the EIAO's analysis of the significance of those findings under the regulations that result in not meeting the requirements of the Acts, and what they show about the establishment's ability to produce safe products

The executive summary is to emphasize your recommendation and include only the essential or most significant information to support that recommendation. You will draw content from the decision-making analysis section and each of the tool summaries to help you write the summary.

It should NOT be a reiteration of the decision-making analysis, nor should it introduce any information that is not contained in the FSA report.

A Good Method for Measuring the Effectiveness of Your Executive Summary

Imagine that the executive summary is the only part of the FSA report that anyone can see and then ask the question: Does the summary adequately explain and support the recommendation?

An Executive Summary Dissected

A Sentence or Two that Describes the Establishment and Its Processes

Shaw Foods, Inc., is a large establishment utilizing pork slaughter, raw non-intact, raw intact, heat treated shelf stable, fully cooked not shelf stable, and heat treated not fully cooked processes. Products include fabricated raw pork, pork trimmings, textured pork, lard, sliced cooked ham and Canadian bacon, and bacon. The establishment produces post-lethality exposed ready-to-eat products using Alternatives 2 (potassium lactate/sodium diacetate) and 3.

A Sentence or Two That Describes the Establishment's Compliance History

The establishment had no enforcement actions over the past 12 months. Our analysis of the 7 sanitation noncompliance reports (NR) over the previous 6 months revealed no trend of noncompliance.

A Sentence that Describes Sampling Results, If Applicable

No positives for FSIS verification sampling for *Listeria monocytogenes* have been identified in the past 12 months. Additionally, the plant is in Category 1 for *Salmonella* sample sets.

A Couple of Sentences that Describe Major Findings Leading to the Recommendation

Our thorough analysis of the FSA findings supports a recommendation of NRs written by in-plant inspection personnel. The establishment did not have a procedure within the fully-cooked not shelf-stable HACCP plan to document the results of CCP 2B (cooking) and CCP 3B (chilling) as required by 9 CFR 417. The establishment was documenting the results as part of a program outside the HACCP plan corresponding to 417.2(c) (4) and 417.2(c) (6) noncompliances (NR #XXXX-XXXX-XXXX). The establishment was following the program, and the program was adequately supported (direct observation, discussion with establishment personnel, and document review), so there were no food safety concerns.

A Couple of Sentences Analyzing Findings and Their Significance

With the exception of the noncompliance discussed above, the operational and preoperational observations, as well as records reviewed during the assessment for all HACCP plans, indicate the establishment is implementing

its food safety system according to its written procedures. The establishment based these programs on determinations it made after conducting hazard analyses to determine the food safety hazards reasonably likely to occur in each respective production process. The establishment has developed measures to control all hazards identified as reasonably likely to occur. The CCPs, including the critical limits, are fully supported and validated. These data, in total, demonstrate that the establishment is in compliance at present, with the exception of the recommended NRs cited above.

NOTE: If noncompliance had an effect on food safety—for example, the possibility that contaminated product was shipped—this would be added to the final portion of the executive summary.

Example of an Executive Summary

Montgomery Burn's Foods USA is a small establishment producing Raw Intact, Raw Non-Intact, and Fully Cooked–Not Shelf Stable products. Products include fabricated raw and RTE beef, pork, chicken, and turkey products. All RTE post lethality exposed products are produced under Alternative 3.

This FSA was conducted to assess changes that may have occurred in the food safety system due to the change in ownership of the establishment. The establishment has had no enforcement actions since the change in ownership (01/09/15). Analysis of the 3 noncompliance reports (NRs) over the previous 5 months indicated no trend of noncompliance.

The food safety assessment included review of all HACCP plans, SSOPs, facilities, Recall Program, and Food Defense Plan. Analysis of the RTE HACCP plan indicated failure by the establishment to support the design of the HACCP plan, therefore failing to meet the requirements of Part 417.5(a)(2).The following vulnerabilities associated with the production process were identified. Once non-meat ingredients (spices, breadcrumbs, etc.) are removed from the dry storage area, they are placed in bins for dispensing, exposing these ingredients to high moisture levels. The establishment has not addressed the potential for changes in ingredients' moisture levels during long storage periods, which may allow for pathogen, mold, and/or yeast growth.

The findings noted during the assessment indicate failures by the establishment to support the design of the food safety system. Review of FSIS's and the establishment's test results, HACCP, and SSOP records did not indicate an immediate threat to product safety. Actual in-plant observation of monitoring and verification activities support the absence of immediate food safety concerns, yet the establishment has a responsibility to support the adequacy of the design of their food safety system and maintain documentation to demonstrate the proper implementation and effectiveness of that design as required by Part 417.5. There were no issues of noncompliance creating an imminent threat to food safety that warranted a recommendation for an enforcement action in accordance with the Rules of Practice. No further action is recommended.

(334 words; 2,222 characters with spaces)

Exercise: Executive Summary Critique and Rewrite

Read and critique this executive summary. What works well? What changes might you make? Critique and then rewrite this executive summary as you believe it should be written. Be prepared to share your rewrite.

Meat and poultry products are an important part of the Nation's supply of food. They are consumed throughout the nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of the consumers be protected by assuring that meat and poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. (21 U.S.C. 602).

To meet this objective, Enforcement Investigation Analysis Officers (EIAOs) verify the sanitary conditions of such establishments by performing Food Safety Assessments, 21 U.S.C. 608, which states, "*The Secretary shall cause to be made, by experts in sanitation or by other competent inspectors, such inspection of all slaughtering, meat-canning, salting, packing, rendering, or similar establishments in which cattle, sheep, swine, goats, horses, mules and other equines are slaughtered and the meat and meat food products thereof are prepared for commerce as may be necessary to inform himself concerning the sanitary conditions of the same, and to prescribe the rules and regulations of sanitation under which such establishments shall be maintained; and where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as "inspected and passed".*

The Federal Meat Inspection Act, 21 U.S.C. 608 and Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) gives the Secretary the authority to prescribe rules and regulations (CFR 416 and 417), requiring sanitary practices in official establishments. 21 U.S.C. 608 also gives the Secretary the authority to refuse inspection to any establishment who fails to meet the requirements 21 U.S.C. 601(m)(4) and 21 U.S.C. 453 Section 4(g)(4) describes product as adulterated if it has been produced, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

B. Gumble's, Establishment #ABC123, is a very small red meat slaughter facility. The establishment slaughters multiple species (beef, goats, lamb, and hogs) for distribution to restaurants and supermarket sales using the Raw-Red Meat Slaughter HACCP category. The establishment's predominant species is goat. All products are sold as whole carcasses and the establishment does not process bench trim, raw-intact or raw-non intact products at this time. The establishment had no enforcement actions within the last year. The establishment's grant of inspection was issued April 2, 2014. This is the first Food Safety Assessment being performed at this establishment.

The establishment has a written SSOP plan in accordance with the regulatory requirements of 9 CFR Part 416.11. Direct observations of the facility and equipment showed that the establishment is maintained clean and sanitary. There was no evidence during this FSA of any deficiencies that would cause a public health concern.

Direct observations and a complete review of the establishment's Red Meat Slaughter HACCP plan and records by the EIAO showed that the establishment's Red Meat Slaughter HACCP plan meets the basic regulatory requirements of 9 CFR Part 417 at this time. The establishment is implementing their humane handling and sanitary dressing procedures as their programs and FSIS regulatory requirement state. However, the establishment is not testing and documenting the acetic acid mixture concentration being used as an antimicrobial agent. This could be a weakness in the establishment's HACCP system. An NR is recommended to address this non-compliance.

The establishment is sampling their goat carcasses for generic *E. coli* by the surface swab method. The establishment has had no positive test results for antibiotic residues and all *E. coli* sample results are negative. Direct observations and records reviewed showed that the establishment is addressing SRM removal as per regulatory requirements. Direct observations and complete review of the establishment's Red Meat Slaughter HACCP plan and records showed that the establishment's HACCP plan with the one exception noted meets the regulatory requirements of 9 CFR Part 417 at this time.

The overall assessment of the establishment and the food safety plans in operation is one that operates in compliance. There were no HACCP deviations documented by FSIS in-plant inspection personnel. There was one HACCP deviation observed in the HACCP records for CCP#2 by the EIAO during this assessment. The establishment's SSOPs, SOPs, *E. coli* control, Sanitary Dressing and SRM programs along with the HACCP plan meets the regulatory requirements of 9 CFR Parts 416, 417, and 310 at this time. Direct observations and records reviewed of the establishment's food safety systems in operation at this time; provide the basic environmental conditions for the production of safe, wholesome food and no issues affecting public health were observed. The final recommendation is that an NR be issued with a follow up visit in 30 days to assure that the possible titration weakness at CCP#2 be corrected.

The follow-up visit will be conducted with the FLS in approximately 30 days. Corrective actions for the non-compliance are to be implemented by June 29, 2015.

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Suggested Response for Executive Summary Rewrite

B. Gumble's, Establishment #ABC123, is a very small establishment that slaughters multiple species (beef, goats, lamb, and hogs) for distribution to restaurants and supermarket sales using the Slaughter HACCP category. The establishment's predominant species is goat. All products are sold as whole carcasses and the establishment does not process bench trim, raw-intact or raw-nonintact products at this time. The establishment had no enforcement actions within the last year. The establishment's grant of inspection was issued April 2, 2014. This is the first Food Safety Assessment being performed at this establishment.

The establishment has a written SSOP plan in accordance with the regulatory requirements of 9 CFR Part 416.11. Direct observations of the facility and equipment showed that the establishment is maintained clean and sanitary. There was no evidence during this FSA of any deficiencies that would cause a public health concern.

Direct observations and a complete review of the establishment's Red Meat Slaughter HACCP plan and records by the EIAO showed that the establishment's Red Meat Slaughter HACCP plan meets the basic regulatory requirements of 9 CFR Part 417 at this time. The establishment is implementing their humane handling and sanitary dressing procedures as designed. The establishment collects surface swab samples from their goat carcasses and tests for generic *E. coli*. The establishment has had no positive test results for antibiotic residues and all *E. coli* sample results were negative. Direct observations and records reviewed showed that the establishment is addressing SRM removal, per regulatory requirements

Based upon this food safety assessment, one NR is recommended for a HACCP deviation that was observed in the HACCP records for CCP#2, Antimicrobial Spray Application. Specifically, the establishment is not testing and documenting the acetic acid mixture concentration being used as an antimicrobial agent. This could be a weakness in the establishment's HACCP system, and an NR by IPP is recommended to address this non-compliance, with a planned follow-up in 30 days by the FLS.

(348 words)

Exercise: Evaluate and Rewrite an Executive Summary

Please read, evaluate, and then rewrite the following executive summary.

Bouvier Fine Meats Inc. is a small establishment utilizing Raw Non-Intact meat, Raw Intact meat and poultry, Retail exempt and Custom Exempt processes. Raw Non-Intact products include ground beef, pork, lamb, sausage, and buffalo. Raw Intact products include beef, pork, lamb, veal cuts, poultry, and buffalo. This Food Safety Assessment (FSA) for cause due to a request by the Frontline Supervisor for changes in the food safety system. The establishment has not had any enforcement actions or complaints over the past 12 months. Analysis of 1 (one) sanitation performance standard (SPS) and one (1) sanitation standard operating procedures (Sanitation SOP) noncompliance records (NRs) over the previous 6 months revealed no trend of noncompliance. There have been no positives for FSIS verification sampling.

A thorough analysis of the FSA findings supports a recommendation that a Notice of Intended Enforcement be issued. The establishment conducted a Hazard Analysis that failed to support the decision that *E. coli* O157:H7 is not reasonably likely to occur for both the Raw Non-Intact and the Raw Intact process categories per 9 CFR 417.2 (a) (1).

Bouvier Fine Meats receives raw beef products (boxed beef and carcasses) intended for non-intact uses of grinding and needle tenderization. Bouvier Fine Meats has determined in the hazard analysis that the pathogen *E. coli* O157:H7 is not reasonably likely to occur at receiving. They support this decision by citing several research papers that have outlined that *E. coli* O157:H7 has a low prevalence in these types of products. Letters of Guarantee and third-party audits received on a yearly basis from suppliers constitute additional support for their decision.

E. coli O157:H7 is considered an adulterant in non-intact beef. On January19, 1999, FSIS published a policy statement, “Beef Products Contaminated with *E. coli* O157:H7” (64 FR 2803). This document reiterated that ground beef is adulterated if contaminated with *E. coli* O157:H7. It also stated beef products mechanically tenderized are adulterated if contaminated with *E. coli* O157:H7.

Recent documented recalls and human illness for non-intact beef products contaminated with *E. coli* O157:H7 provides historical evidence that adulteration of product occurs. Because it has historically occurred for the types of products they produce, Bouvier has failed to meet 9 CFR 417.2 (a) (1) which states, “A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred…”

Bouvier has also failed to meet nine CFR 417.4 (a). They have failed to perform meaningful, on-going, activities to verify that the HACCP plan is being effectively implemented. The LOG and third-party audits are received from supplying establishments on a yearly basis. Bouvier is relying on the information provided in the LOG and audits to support the decision that *E. coli* O157:H7 is unlikely to occur. The LOG state that suppliers are applying interventions to reduce *E. coli* O157:H7 to undetectable levels. The sporadic low-level occurrence of *E. coli* O157:H7 requires frequent verification to provide assurance that the pathogen is being successfully prevented. Bouvier does not conduct frequent on-going communications with suppliers that would give them the information and assurance the interventions and controls in place are effective reducing *E. coli* O157:H7 to a non-detectable level.

Bouvier does test on a random basis product from two suppliers per month for indicator organisms, not *E. coli* O157:H7. They are using this data to confirm sanitary conditions of the suppliers and not as a reason that *E. coli* O157:H7 is unlikely to occur. One of the Suppliers of Carcasses performs *E. coli* O157:H7 testing consisting of 300cm^2 swab on everyone 1 out of 300 carcasses. There is no evidence that this is considered robust testing or if it is representative of the lots of beef sent to Bouvier.

Bouvier has a program to spray intact beef (Box beef subprimals and carcasses) intended for non-intact use (tenderization and grinding). This program utilizes an acidified sodium chlorite (ASC) spray cabinet for subprimals and hand sprayer for carcasses that is validated to provide 1 to 2 log reductions in *E. coli* O157:H7. It is utilized as a processing aid only and not to control *E. coli* O157:H7 except in the unlikely chance it has contaminated product. The establishment recognizes that there is a possibility incoming raw beef products can be contaminated with the adulterant *E. coli* O157:H7 but considers the likelihood small enough to consider it unlikely to occur. When the CFSA started the establishment had not been spraying carcasses. By the end of the CFSA they indicated they were going to start the carcass spray. The ASC spray cabinet lacked support for the overlapping of subprimals on the conveyor and the subsequent observation that not all the surface was being contacted with ASC as required by the supporting documentation as per 417.5 (a) (1). Support was also lacking in regard for a lack of a written program and records designed to confirm LOG are on file for shipments received. Bouvier also failed to follow the supporting program “Approved Supplier program” which requires beef products intended for grinding to be accompanied by a COA (negative test results for *E. coli* O157:H7) or be held until tested for *E. coli* O157:H7. Carcasses received and further processed for grinding are not received with COA’s or held for *E. coli* O157:H7 testing.

Bouvier Fine Meats, Inc. has an inadequate HACCP system per 417.6 (a). They consider *E. coli* O157:H7 unlikely to occur for non-intact beef products and have failed to support that decision. Bouvier Fine Meats relies on scientific articles, yearly LOG, and third-party audits to lend support to their decision. Historical evidence has shown the types of products produced at Bouvier Fine Meats have been implicated in recalls and human illness associated with *E. coli* O157:H7 adulteration. *E. coli* O157:H7 contamination of product may occur at a sporadic and low level but that only indicates frequent verification is necessary to provide assurance the pathogen is being successfully prevented. Bouvier lacks evidence that frequent on-going communication with suppliers is occurring. Other than yearly LOG and third party audits there is no significant communication or data between Bouvier and its suppliers that would lend assurance that consistent and effective controls are in place to ensure *E. coli* O157:H7 is not present at a detectable level in product being received. Additionally, supporting documentation is lacking that LOG are confirmed for incoming products and the ASC spray cabinet being operated outside the parameters of supporting documentation. (1116 words)

Notes Page

Suggested Rewrite of "Evaluate and Rewrite an Executive Summary" Exercise

Bouvier Fine Meats, Inc. is a small establishment utilizing Raw Non-Intact, Raw Intact and Poultry, Retail Exempt, and Custom Exempt processes. Its Raw Non-Intact products include ground beef, pork, lamb, sausage, and buffalo. Its Raw Intact products include beef, pork, lamb, veal cuts, poultry, and buffalo. FSIS performed this Food Safety Assessment (FSA) for cause based on a request by the Frontline Supervisor because of changes in the food safety system. The establishment has had no enforcement actions or complaints over the past 12 months. Our review of two noncompliance reports (NRs)—one for sanitation performance standard (SPS) and one related to its sanitation standard operating procedures (SSOP)—over the previous 6 months revealed no trend of noncompliance. There have been no positives for FSIS verification sampling.

The FSA findings support a recommendation that a Notice of Intended Enforcement be issued. The establishment conducted a hazard analysis that failed to support the decision that *E. coli* O157:H7 is unlikely to occur for both the Raw Non-Intact and Raw Intact processes per 9 CFR 417.5(a)(1) and 417.2(a)(1).

Bouvier Fine Meats, Inc. Food Safety System would be characterized as an inadequate HACCP system per 417.6 (a). They consider *E. coli* O157:H7 unlikely to occur for non-intact beef products and have failed to support that decision. The establishment relies on scientific articles, yearly Letters of Guarantee (LOG), and third-party audits to support its decision. However, Bouvier lacks evidence of frequent on-going communication with suppliers. Other than yearly LOG and third-party audits, there is no significant communication or data between Bouvier and its suppliers to ensure consistent and effective controls are in place, thus ensuring *E. coli* O157:H7 is not present at a detectable level in received product.

Bouvier also failed to follow the "Approved Supplier Program," which requires beef products intended for grinding to be accompanied by a Certificate of Analysis (COA) with negative test results for *E. coli* O157:H7 or to be held until tested for *E. coli* O157:H7. Carcasses received and further processed for grinding are not received with COAs or held for *E. coli* O157:H7 testing by Bouvier. Because of these findings, we recommend the issuance of a Notice of Intended Enforcement as described in 9 CFR 500.4(a). Therefore, the inadequate design of the Food Safety System may result in the production of adulterated product as described in The Federal Meat Inspection Act (FMIA) 21 United States Code (USC) 601, Section 1(m)(4).

Information on Writing Sample Above:

- *354 words, 20.8 words per sentence, 4.2 sentences per paragraph*
- *5% passive voice, 13.1 Grade Level Score, 37.5 Reading-Ease Score*

Format for Writing Notice of Intended Enforcement (NOIE) and Suspension Letters

First Paragraph: What Action FSIS is Taking

Clearly state the purpose of the letter, either FSIS's intent to take enforcement action or that FSIS is withholding the marks of inspection and suspending the assignment of inspectors. Keep this paragraph short. Do not include detailed regulatory language in this paragraph. If you wish, include a "roadmap" sentence that tells the reader what to expect section by section, including the fact that action is required.

Second Paragraph: FSIS's Authority to Take Action

This paragraph (or paragraphs, if needed) outlines the applicable sections of the FMIA, PPIA, or EPIA that give FSIS the authority to initiate this enforcement action under the Rules of Practice. Be certain that the cited provisions reflect the findings outlined in the letter.

Third Paragraph: Findings and Basis for Action

This section describes the reason for the violation. It should include references to establishment documentation, processes, the public health significance of the violation, and why the establishment's actions to address the violation are inadequate. Be sure to cite the specific title of the applicable regulatory requirement (such as 9 CFR 416.3) for each violation, as well as the specific title of the USC and applicable paragraph of the statute.

When there are multiple findings, organize this section using sub-heads. Likewise, use bullet points for lists of related material, such as multiple NRs.

Fourth Paragraph: Alleged Violator's Next Steps and Appeal/Hearing Rights

This final section spells out to the alleged violator what rights he or she has and what actions he or she can take to respond to the NOIE or suspension letter.

Example of a Notice of Suspension

Dear Mr. DENT:

This letter serves as official notice that the Food Safety and Inspection Service (FSIS) is withholding the marks of inspection and suspending the assignment of inspection program personnel at your establishment, Est. 0000 R. O. DENT Co. Incorporated. The following letter provides information on FSIS's statutory authority, our findings, and next steps you may take.

Statutory Authority

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and Poultry Products Inspection Act (PPIA) (21 U.S.C. 454 et seq.) provides that it is essential for the public interest that the health and welfare of consumers be protected by assuring that meat products distributed to them are wholesome, not adulterated, and properly marked, labeled and packaged. These Acts give FSIS the authority, as designated by the Secretary of the Department of Agriculture, to prescribe rules and regulations describing sanitation requirements for inspected establishments. They also provide FSIS program personnel the authority to refuse to allow meat or meat food products to be labeled, marked, stamped, or tagged as "inspected and passed" and to prevent the entry of products into commerce when the sanitary conditions of any such establishment are such that products are adulterated. Furthermore, the Acts provide FSIS the authority to appoint inspectors from time to time to examine and inspect products, including the sanitary conditions of facilities. They also give FSIS program personnel the right to examine and inspect all carcasses and parts of carcasses that are further treated and prepared and the right to access and examine establishment records. When the sanitary conditions of a facility are not properly maintained, FSIS can refuse inspection and indefinitely withdraw inspection from an establishment provided the establishment is afforded the right to an administrative hearing.

Under the authorities of these Acts, FSIS has prescribed rules and regulations required for establishments producing meat products, including the requirements pertaining to Sanitation Standard Operating Procedures (SANITATION SSOP) and Sanitation Performance Standards (SPS) (9 CFR Part 416), and other matters.

FSIS has also developed Rules of Practice regarding enforcement (9 CFR Part 500). The Rules of Practice describe the types of enforcement action that FSIS may take and include procedures for taking a withholding action and/or suspension, with or without prior notification and for filing a complaint to withdraw a Grant of Federal Inspection. FMIA and PPIA contain similar language FMIA 21 U.S.C 601, Title 1, Section 1(m)(4), which defines adulteration as "If it has been prepared, packed, or held under unsanitary conditions, whereby, it may have become contaminated with filth, or whereby, it may have been rendered injurious to health." PPIA 21 USC 454

Section 4 (g)(4) defines adulteration if it has been prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health.

Findings and Basis for Action

FSIS is basing this decision on findings of rodent infestation and insanitary conditions at your establishment. FSIS is presenting this notification as authorized by the Rules of Practice in accordance with 9 CFR 500.3 (a) (4).

The following outlines FSIS's findings at your establishment, including multiple non-compliance records.

- NR 0015-2006-9999, June 23, 2006: FSIS personnel observed several rodent droppings in the chemical storage room, in the mechanical room adjacent to the main processing room, and on a pallet containing packaging materials. FSIS inspection personnel rejected the affected packaging materials and detained the product. The inspector took regulatory control action on the entire facility due to the insanitary conditions created by the rodent infestation as follows: storage rooms using US-Reject tags # B-11111 and B-2222, packaging material using US- Reject tag # B-3333, mechanical room using US- Reject tag # B-4444, and chemical room using US- Reject tag # B-5555.

- NR 0014-2006-9999, June 20, 2006: FSIS observed a small rodent running across a production room floor. There were no affected products or packaging material. Personnel rejected the room with US-reject tag B-123456.NR

- 0013-2006-9999, June 09, 2006: FSIS observed rodent droppings in the dry storage room underneath an unused packing machine and rejected the room with US-Reject tag # B-457689.

- NR 0011-2006-9999, May 20, 2006: FSIS observed rodent droppings in the storage room in contact with two stacks of packaging boxes. FSIS rejected the chemical room using US-Reject tag # B-7891011, the packaging material with US-Reject tag # B-987654, and the dry storage areas with US-Reject tag # B-8765432 and US-Reject tag # B-678912.

- NR 0009-2006-9999, May 4, 2006: FSIS observed rodent droppings on top of packaging materials in the storage room. FSIS personnel rejected the storage room using US-Reject tag # B-876543, as well as rejected the effected packaging materials. A large gap was identified underneath the roll-down gate to the outside of the facility.

Steps You May Take

This suspension of inspection will remain in effect until you provide adequate written corrective and preventive measures that will ensure your meat and poultry products are produced in accordance with the FMIA, PPIA, and the regulations promulgated thereunder.

For inspection to resume at your establishment, you must submit to my attention corrective actions that include the following.

1. Procedures to ensure appropriate disposition of the products that may be contaminated and to ensure no product that is injurious to health or otherwise adulterated as a result of the rodent infestation enters commerce.
2. A detailed assessment of the Sanitation SOP and a review of other sanitation failures at your plant.
3. Specific changes to be made to your SPS.
4. Monitoring activities you will take to ensure your changes are effective.

You are reminded that as an operator of a federally inspected plant you are expected to comply with FSIS regulations and to take appropriate corrective actions to prevent the production of adulterated products at your establishment. Please be advised you have the right to appeal this matter. If you wish to appeal, you should contact:

Executive for Regulatory Operations
USDA/FSIS/OFO
1400 Independence Avenue S.W.
Room 3157, South Building
Washington, DC 20250-3700
Telephone: (202) 720-3697
Fax: (202) 690-3287

In accordance with 9 CFR 500.5(d), you may request a hearing concerning this action by contacting:

Director
Evaluation and Enforcement Division
Office of Program Evaluation, Enforcement and Review
Food Safety and Inspection Service
United States Department of Agriculture
Congressional Quarterly Building Room 300
Washington, DC 20250-3700
Telephone: (202) 418-8872
Fax: (202) 418-8896

If you have any questions regarding this matter, please feel free to contact XXX.

All about Email

Interesting Statistics

- Over a messaging system's lifetime—estimated at 3.5 years—the per-message cost for desktop users is 54 cents. *Source: Creative Networks*

- The cost of acquiring, deploying, managing, administering, and using a messaging system is about $4,200 per user per year. *Source: Creative Networks*

- About 130 million workers in the US send 2.8 billion email messages a day, and 50% report receiving racist, sexist, pornographic, or otherwise inappropriate email at work. *Source: "The e-Policy Handbook," by Nancy Flynn*

- Twenty-seven percent of Fortune 500 companies have defended themselves against claims of sexual harassment stemming from inappropriate email. *Source: "The e-Policy Handbook," by Nancy Flynn*

- "Cyber loitering" is on the rise. Workers with access to the Internet spend the equivalent of 21 working days a year web surfing. About 64% of that time is used for "non-work related entertainment." *Source: Georgia Tech College study*

- A study by Atlassian, the developer of team collaboration software, found that professional workers receive an average of 304 emails a week and check email 36 times an hour.

- A study on interruptions in the workplace found the following:

    - People spend about 20 seconds concentrating on a single item before moving on to another.
    - On average, workers have eight screens open on their computers—for example, email messages, Web pages, Word documents, or PowerPoint files.
    - Many people do not return to the work they were doing and, if they do, it can take up to 15 minutes to refocus.

    Source: Mary Czerwinski, scientist at the Microsoft Research Lab and a leading expert in "Interruption Science"

Deciding When to Use and When Not to Use Email

Situations where email makes the best sense:

- You need to get announcements to a set group of people.
- You need an informal written record.
- You need to communicate across time zones.

Others?

Situations where email does not make the best sense:

- You need privacy.
- You need to watch the other person's body language.
- You are concerned that the message might be misunderstood or misconstrued.
- You have anything negative to say.

"Best Practices" for Writing Email

1. Write the email, and then let it "cool." Do not yet complete the "To" line.
2. Review the email. Did you include a greeting and a closing? Is the purpose and/or request obvious? Does the text need formatting? Are there typos? Use the spelling and grammar-checking function.
3. Check for attachments. Do you need to add any?
4. Finally, send the email, ensuring it is headed to the correct person.

Bottom Line:

All email should pass the "Washington Post" test, regardless of whether it is sent via your work or home computer or via a smartphone. Simply put, to pass the "Washington Post" test (or your preferred national news source), you would be willing to have anything in your email on the cover of the newspaper or on the webpage of a major news source.

What Should Never Go in an Email

- Criticism
- Chain Letters
- Profanity
- Religious Messages
- Political Information
- Anything of a Sexual/Pornographic Nature
- Jokes (unless they are completely non-discriminatory)
- Discriminatory Comments
- Sales or Marketing Materials from Outside Businesses

Email Management Tips

- Get to know the Microsoft Outlook system and all its features.
- Call or visit instead of sending an email, especially if you don't want or need a paper trail, the matter is simple, or the recipient is within proximity.
- Generally, choose to reply without attachments but with the original message to create a thread of meaning.
- Provide context by replying with the original sender's message and by using key words from the original message.
- Send and reply only to those who MUST get the email message.
- Use simple formatting to upgrade your email.
- Make an effort to respond to emails within 24 hours, if possible. If you will be out of the office, use the "Out of Office" reply option.
- Plan your day around small periods of writing and responding to email.
- Consider turning off pop-up notification if you find it distracting.
- If possible, "touch" each email just once. Here are some ways of coping with each piece of email:

    - Read it and delete it.
    - File it in the appropriate folder (by project, person, event, and so on).
    - Act on the "softballs."
    - Forward and delegate the action, as required.
    - Print a hard copy and file it if considered a record.

“AHA!” and Goals Page

APPENDICES

Appendix A: Confusing Words

1. The others will (accept, except) your invitation only if you serve lunch.
2. Please give me some good (advice, advise).
3. Her charm had its intended (affect, effect); she's now wearing a huge diamond ring.
4. It is (apt, liable, likely) that she will charge him for hitting her car.
5. This (coarse, course) is tough to travel on a bike.
6. A thin mint is the perfect (complement, compliment) to a hearty meal.
7. Al met with the (consul, council, counsel) to discuss the best strategies for improving the trade imbalance with Japan.
8. (Because of, Due to) the Big, Bad Wolf, we cannot hike through the woods.
9. I am (anxious, eager) to get home and eat my favorite dessert.
10. She wants to (farther, further) her education so she can go (further, farther) in life.
11. Tommy has (fewer, less) teeth than Zachary.
12. Always read the (forward, foreword) or you may miss something vital about a book.
13. David's cheap car and ragged clothes are a/an (allusion, delusion, illusion); he is really a very wealthy person.
14. Lucy makes those subtle, little comments to (infer, imply) that I am a hussy.
15. (It's, Its) not fair that you got the last piece of pizza.
16. He was not feeling well so he (lay, laid) down.
17. Do not (lose, loose) that key or we will have to call for a spare.
18. People always say it is the (principal, principle) of the matter, but they are actually worried about losing money.
19. Placing first, second, and third were Tim, Allan, and Sam (respectfully, respectively).
20. Do not just (set, sit) there; (set, sit) that tray down and we can dance!
21. She was shocked at the expense of the (stationary, stationery).
22. I was (to, too) elated to care about the dent in my car.
23. The person (who, which, that) called me last night is a complete fool.
24. Pat dances (well, good), but she is not a (good, well) singer.
25. Norma is (sure, surely) a successful lawyer.
26. Hugh was (real, really) pleased to win the contest.
27. The pressures of college are different (from, than) the pressures of work life.
28. I will (bring, take) it with me when I go.
29. If you bring the teacher (a, an) ukulele, he is likely to give you a good grade.

30. If you finished your homework (already, all ready), then we can get the van (already, all ready) to go on our vacation.
31. Maury said the answers were (alright, all right).
32. (Alot, A lot) of people crowded the food truck at noon.
33. We traveled (altogether, all together) to the White House and were (altogether, all together) pleased when we saw the President wave to us.
34. She told me that I should use (anyway, any way) possible to get to the concert even though I did not want to go (anyway, any way).
35. A letter takes an (attachment, enclosure) and a memorandum takes an (attachment, enclosure).
36. I sat (between, among) two handsome triathletes while my sister stood (between, among) eight rugged rugby players.
37. I (can, may) do this assignment today, but (can, may) I submit it online?
38. The data (is, are) available tomorrow.
39. I will (try and, try to) meet you at the cafeteria at noon.
40. She (would have, would of) printed her paper if the power was on.

Confusing Words Defined

1. accept: to take or to agree to
   except: to omit or exclude

2. advice: information or suggestion (noun)
   advise: to offer an opinion or to counsel (verb)

3. affect: to influence (verb); behavior or mood (noun/psychological term)
   effect: a result, or outcome (noun); to bring about (verb)

4. apt: appropriate or pertinent
   liable: exposed to damage; responsible
   likely: probable

5. coarse: rough
   course: path

6. complement: to complete
   compliment: expression of respect or praise

7. consul: officer residing in a foreign country to promote his/her own country's interests
   counsel: an exchange of opinion; one who advises; to give advice
   council: an assembly of persons

8. due to: payable to; owed
   because of: by reason of

9. eager: enthusiastic
   anxious: apprehensive; nervous

10. farther: a greater distance
    further: an extension of time or degree

11. fewer: smaller in number; things you can count
    less: smaller in size or bulk; things you cannot count

12. foreword: a preface or explanation at the beginning of a book or report
    forward: situated near the front; to advance (verb)

13. illusion: deceptive appearance
allusion: a casual reference
delusion: deceit

14. imply: to insinuate or express indirectly
infer: to conclude from what was said (The speaker implies; the hearer infers.)

15. its: possessive form of pronoun "it"
it's: contraction of words "it" and "is"

16. lie: intransitive verb (takes no object) meaning to recline one's body; lie/lay/lain
lay: transitive verb (takes an object); lay/laid/laid

17. lose: to fail to keep
loose: not rigidly fastened

18. principal: occupying the first rank
principle: fundamental truth or doctrine

19. respectfully: with respect
respectively: singly considered, in this specific order

20. sit: intransitive verb meaning to put your bottom down
set: transitive verb meaning to put an item someplace

21. stationary: fixed in place
stationery: paper and other writing materials

22. to: preposition of direction
too: adverb that describes the degree or amount

23. who: refers to people, that--refers to people, animals, or things
which: refers to animals or things

24. good: describes nouns (adjective)
well: describes verbs (adverb)

25 sure: an adjective meaning to be certain
surely: an adverb meaning certainly

26. real: an adjective meaning genuine
really: an adverb meaning extremely, usually modifies an adjective

27. different from: the correct usage for comparing different things.

28. bring: indicates movement toward speaker.
take: indicates movement away from the speaker

29. a: used in front of words with a consonant sound such as snake
an: used in front of words with a vowel sound such as hour or apple

30. all ready: to be fully prepared
already: having already occurred

31. all right: in satisfactory order (*alright* is the incorrect form)

32. a lot: a significant amount (*alot* is the incorrect form)

33. altogether: completely or thoroughly
all together: in a group, in unison

34. anyway: regardless, nonetheless (*anyways* is not a word)
any way: using whatever means possible

35. attachment: additional information included with a memorandum
enclosure: additional information included with a letter

36. between: used with to people or things
among: used with more than two people or things

37. can: expresses ability
may: expresses permission

38. data: plural noun meaning a group of facts; use *are* not *is*

39. try to: this is the correct form; do not use *try and*

40. would have: this is the correct form; do not use *would of*

Appendix B: Transition Words and Phrases

Common Transitions

CAUSE	EFFECT	CHOICE
Because	As a result	Or
Since	Therefore	Alternatively
As	Consequently	Instead
For	Thus	Either…or
Due to	Accordingly	Neither…nor
Thus	So…that	
On account of	Such a…that	

ADDITION	CONTRAST	COMPARISON
And	But	Similarly
Also	However	Likewise
Too	Instead	In the same way
As well as	Yet	Just as…so
Besides	Otherwise	
In addition	Nevertheless	
Moreover	Except for	
Furthermore	In spite of	
Including	Despite	

ILLUSTRATION	SEQUENCE	TIME
For example	First	Now
Specifically	Next	Then
For instance	After	Later
In other words	Ultimately	Currently
In particular	Before	Meanwhile
That is	Finally	Earlier

PLACE	CONDITION	DURATION
Here	If	To some extent
There	Even if	To some degree
At this point	Although	To date
Below	Unless	Up to now
Next to	Supposing that	So far
In front of	Given that	Until
Alongside	Assuming that	

Appendix C: Say It Simply

DIFFICULT	**SIMPLE**
Additional	More
Aforementioned	Cited
Allocate	Give, divide
As per	According to
Assistance	Help
Cease	Stop
Deem	Consider
Employ	Use
Endeavor	Try
Facilitate	Help
Furnish	Give
Herein	Here
Heretofore	Until now
Implement	Carry out
Indicate	Show
In lieu of	Instead of
In the event that	If
Issue	Give
Necessitate	Require
Notification	Notice
On behalf of	For
Per annum	A year
Possess	Have
Prior to	Before
Proceed	Go ahead
Procure	Get
Provided that	If (or change sentence)
Pursuant to	Under
Regarding	About
Represents	Is
Retain	Keep
Submit	Send
Subsequent to	After
Terminate	End
To the extent that	If, when
Transmit	Send, give
Utilize	Use
With regard/respect to	For

Appendix D: Punctuation Review

Apostrophe (‘)

1. Use (or the apostrophe and s) to indicate possession.
   To form the possessive case of a singular or plural noun not ending in s, add an apostrophe and s, as in the Administrator’s meeting.

   To form the possessive case of a singular or plural noun ending in s or with an s sound, add an apostrophe only, as in James’ coat (one person’s coat) or the girls’ lockers (many girls with lockers).

   Be cautious with irregular plural forms not ending in s, as in men’s room or children’s party.

2. Use to indicate omitted letters in contractions, shortened words, and abbreviated dates.
   Is Tom a Class of '67 graduate?

3. Use to indicate the plural of uppercase and lowercase letters only when leaving it off would confuse the reader.
   I wish she would cross her t's and dot her i's.

4. Do not use the apostrophe with possessive pronouns.
   The children are theirs, not ours. (Not: The children are their's, not ours’.)

Brackets: [ ]

Use brackets to indicate language that is not part of the original quote, to show a correction, to clarify or explain information, or to guide the reader.
The report contains data on this phenomenon [see pages 12-15].

Colon (:)

1. Use after a complete sentence to introduce a list.
   The investigators brought the following items to document the investigation: pencils, notepads, cameras, tape recorders, and a video camera.

2. Use after a complete sentence to introduce a quotation, summary, or explanation.
   The investigators followed the manual guidelines: “At the beginning of this section, cite the section of the relevant statute that was allegedly violated.”

3. Use to separate the hour and minutes in clock time.
   6:30 a.m. to 5:00 p.m.
   2 p.m., 3 p.m., 6 p.m. but 3:15 p.m. and 5 p.m.
4. Use after the salutation in a formal business letter.
   Dear Dr. Fox: or To Whom It May Concern:

Comma (,)

1. Use to separate main clauses when linked by a coordinating conjunction.
   I was unsuccessful in reaching Mr. Banks on the telephone or via email, so I drove to his business to interview him.

2. Use to separate words or phrases in a series. Use a comma before the conjunction with a series of three or more.
   We interviewed the facility manager, night-shift manager, and day-shift manager.

3. Use with adjectives that can be interchanged (or where you can use and in the middle without affecting the meaning).
   This must be a thorough, impartial report.

4. Use to set off an introductory clause or interjection.
   Oh, you are right. If snow falls, the drive will be slow.

5. Use in pairs to set off nonessential information—information that if left off would not affect the meaning of the sentence. This includes appositives and which statements.
   We interviewed Mr. Thomas Banks, the facility owner, at his office.

6. Use with phrases that begin with terms like as well as and in addition to.
   He had reviewed the market research reports, as well as the export reports.

7. Use commas in pairs to set off degrees and titles.
   William Brown, Ph.D., is the guest speaker.

8. Use to set off dates, places, and addresses. Do not use a comma with just the name of a city, state, or country. Do not use a comma with just the month and year. (January 2017).
   Forward his mail to 2973 Main Street, Tallahassee, Florida, until January 28, 2009.
9. Use to set off a tag question.
   You do like my gift, correct?

10. Use to set off the words said in a direct quotation.
    Sam said, "It's about time you got a job."

11. Use to separate two identical words or two sets of figures.
    Curtis had lost it, it seemed.
    We told you, you might regret doing that.
    Buy me 20, 34¢ stamps and 10, 55¢ stamps.

12. Use to set off words or phrases expressing contrast.
    I want my children to be independent thinkers, not little monsters.
    Lucy always wanted a lucrative position, but never with so many duties attached.

13. Use with direct address.
    Paul, I do not agree with your approach.

Dashes (--)

To use this punctuation mark, hit the hyphen mark twice and do not include a space before, between, or after the hyphens marks. A dash is twice as long as a hyphen and sits lower.

1. Use to mark a sudden break or an afterthought.
   He said—and no one contradicted him—"The battle is lost."

2. Use to indicate more emphasis.
   Many components of the rule—for example, the introductory summary—are written before the regulation text.
   I want my children to be independent thinkers—not little monsters.

3. Use in place of commas or parentheses if the meaning is clarified by the dash.
   These are shore deposits—gravel, sand, and clay—but marine sediment is beneath them.

4. Use to precede a credit line or signature.
   This statement is open to question.—Gerald H. Forsythe

Ellipses (…)

1. Use to show that words or sentences are missing from a quoted passage.
   During the past five years…we have noticed a change in the use of this code.

2. Use to indicate a pause or interruption.
   We can go to the play…if you want to go.

Exclamation Point (!)

Use to indicate the end of a complete thought that expresses surprise, incredulity, enthusiasm, or other strong emotion.
    I am extremely upset right now!

Hyphen (-)

Use it if a pair of words forms an adjective that comes before the noun. The general rule is to use a hyphen between words if the words by themselves would make no sense in connection with the following noun.
third-party witness, FSIS-regulated products

Quotation Marks

1. Use to enclose a direct quotation. Begin a direct quote with an uppercase letter.
   Mr. Sacks stated, “I ordered this product and had it labeled as required.”

2. Use to enclose any words following terms such as “labeled,” "entitled," "marked," or "referred to."
   The product was labeled “Not for Human Consumption.”

3. Use to enclose the titles of short works like magazine articles, short stories, essays, poems, songs, and book chapters.
   The jukebox was playing the Beatles' song "Yesterday."

4. Use to enclose misnomers, slang expressions, nicknames, coined words, or words used in an unusual way.
   My "best friend" had an affair with my husband.

Place commas and periods within quotations. Place colons or semicolons outside quotations unless it is part of the quote.
The water buffalo’s name was "Big Bad Bubba."
I am reading an article called, "Getting Dates"; you ought to read it, too.

Semicolon (;)

1. Use it to connect two related sentences.
   The owner was not present for the interview; therefore, I interviewed the manager.

2. Use it to connect elements in a list when the list has many commas.
   Our training sites include Philadelphia, Pennsylvania; Sacramento, California; and Omaha, Nebraska.

Appendix E: Helpful Resources

Bailey, Edward P., Jr. (1990) *The Plain English Approach to Business Writing*
New York: Oxford University Press

Bivins, Thomas (1996). *Handbook for Public Relations Writing*
Chicago, IL: NTC Business Books

Brereton, John C. and Margaret A. Mansfield (1997). *Writing on the Job*
New York, NY: W.W. Norton and Company

Davidson, Wilma, Ed. D. (1994) *Business Writing: What Works, What Won't*
New York: St. Martin's Griffin

Lauchman, Richard (1993) *Plain Style*
New York: AMACOM

Pearsall, Thomas E. and Donald H. Cunningham (1994) *How to Write for the World of Work*
New York: Harcourt Brace College Publishers

Rubens, Philip (1992 *Science and Technical Writing: A Manual of Style*
New York: Henry Holt and Company

Zinsser, William (2006) *On Writing Well, 30th Anniversary Edition*
New York, NY: Harper & Row, Publishers