

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION ANIMAL FOOD SAFETY INSPECTION AUDIT FORM**

CONTACT INFORMATION

| | | |
|--------------------|-----------------|--|
| AUDITOR | STATE INSPECTOR | |
| FIRM NAME | FEI # | |
| FIRM ADDRESS | | |
| PRODUCT(S) COVERED | DATE | |
| TIME IN | TIME OUT | OVERALL RATING |
| | | <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement |

I. PREINSPECTION ASSESSMENT

1. Did the inspector prepare for the establishment inspection (e.g. review the previous inspection report, possible complaints, and/or access other available resources in preparation for the inspection)?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. Did the inspector have the appropriate equipment and resource materials to properly conduct the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE

1. Was FDA jurisdiction established?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

2. Were appropriate credentials (FDA or state) presented and Notice of Inspection (FDA 482 or state equivalent form) with attachments issued to the firm?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

3. If the firm is a Licensed Medicated Feed Mill, was a copy of the Feed Mill License (FML) and drug registration verified to be active and current? (If this question does not apply, mark as Acceptable.)

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

4. If applicable, did the inspector verify the food facility registration and/or attestation to be a qualified facility? (If this question does not apply, mark as Acceptable.)

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

5. Did the inspector select appropriate product(s) during the inspection focusing on the firm's products and processes determined to be high risk, and if necessary, make appropriate adjustments based on the type of firm being inspected?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

6. Did the inspector evaluate employee activities that may affect safe production and storage of animal food?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

7. Did the inspector evaluate conditions, practices, components and/or labeling that may cause the product to be adulterated or misbranded?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

8. Did the inspector recognize significant violative conditions or practices, if present, and record findings consistent with FDA or state reporting procedures?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

9. Did the inspector demonstrate the ability to distinguish between significant versus insignificant observations and isolated incidents versus trends?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

10. Did the inspector review and evaluate the appropriate records and procedures for this establishment's operation and effectively apply the information obtained from this review?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

11. Did the inspector collect adequate evidence and documentation to support inspection observations in accordance with procedures, if violative conditions were encountered?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

12. Did the inspector verify that deficiencies from the previous inspection were corrected?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

13. Did the inspector act in a professional manner and demonstrate proper safety practices during the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION

1. Did the inspector identify himself/herself and make appropriate introductions, which include explaining the purpose and scope of the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. Did the inspector use suitable interviewing techniques?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

3. Did the inspector explain findings accurately and clearly throughout the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

4. Did the inspector notify the most responsible person at the firm if anything requiring immediate corrective action was necessary?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION (*Continued*)

5. Did the inspector answer questions posed by facility personnel and provide information in an appropriate manner?

Acceptable Needs Improvement

COMMENTS (*required for Needs Improvement*)

6. Did the inspector record findings accurately, clearly, and concisely on the FDA or state inspection report?

Acceptable Needs Improvement

COMMENTS (*required for Needs Improvement*)

IV. ADDITIONAL ANIMAL FOOD REGULATORY PROGRAM STANDARDS (AFRPS) QUESTIONS

NOTE: Only answer these two questions if the state being audited is enrolled in the AFRPS.

1. Did the inspector follow applicable bio-security procedures required by the animal food facility and the FDA/state program?

Acceptable

COMMENTS (*required for Needs Improvement*)

2. Did the inspector recognize relative risk (high to low) of the animal food facility based on the state program's risk-based inspection program and categorization to a facility of a product, the manufacturing processes, and the inspection history of a facility?

Acceptable Needs Improvement

COMMENTS (*required for Needs Improvement*)

IV. NOTES

NOTE: EVERY ITEM MARKED "NEEDS IMPROVEMENT" MUST BE ACCOMPANIED BY AN EXPLANATION OF WHY THE ITEM WAS MARKED AS NEEDING IMPROVEMENT.

Overall Rating:

If three or less items are marked "needs improvement," the overall rating is "acceptable." If four or more items are marked "needs improvement," the overall rating is "needs improvement." The overall rating must be marked in the space provided in the header on the first page.

All questions must be answered "acceptable" or "needs improvement."

If four or more evaluated items are marked as "needs improvement", the State Program Manager must be notified by the appropriate FDA liaison that additional training or other performance measures for the inspector being audited should be initiated. All contract inspectors who receive an overall audit score of "needs improvement" shall receive remedial training in deficient areas or as agreed upon by the FDA Division and OP Project Managers prior to resuming contract inspection duties.

ADDITIONAL COMMENTS

SIGNATURE OF AUDITOR

DATE

APPENDIX J
CORRECTIVE ACTION PLAN for
PROGRAM and INDIVIDUAL PERFORMANCE DEFICIENCIES

| | | |
|---|--|--------------------------|
| | | |
| Program Division | State Liaison | |
| State Agency | State Agency Contact | |
| Period of Performance | Start Date: End Date: | |
| Type of Performance Deficiency Individual (A separate form should be completed for each person receiving an overall needs improvement or unacceptable rating) Program (If a program deficiency occurs in more than 1 program, complete separate forms for each program) | | |
| Inspection Program Type Human Food Egg Animal Food Medical Devices | | |
| | | |
| 1. Description of Deficiency (include the performance factor number from audit form) | 2. Corrective Action (attach additional and supporting information as necessary) | 3. Date Completed |
| | | |
| | | |
| | | |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG
ADMINISTRATION FIELD INSPECTION AUDIT**

| | | | |
|--------------------|----------|--|--|
| AUDITOR | | STATE INSPECTOR | |
| FIRM NAME | | FEI NUMBER | |
| FIRM ADDRESS | | | |
| PRODUCT(S) COVERED | | DATE | |
| TIME IN | TIME OUT | OVERALL RATING | |
| | | <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement | |

I. PREINSPECTION ASSESSMENT

1. Did the Inspector review the state's establishment file for the previous inspection report and possible complaints or access other available resources in preparation for the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. Did the inspector have the appropriate equipment and forms to properly conduct the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE

1. Was FDA jurisdiction established?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

2. Did the inspector select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the firm was producing?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

3. Did the inspector assess the employee practices critical to the safe production and storage of food?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

4. Did the inspector properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

5. Did the inspector recognize significant violative conditions or practices if present and record findings consistent with state procedures?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE (Continued)

6. Did the inspector demonstrate the ability to distinguish between significant versus insignificant observations and isolated incidents versus trends?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

7. Did the inspector review and evaluate the appropriate records and procedures for this establishment's operation and effectively apply the information obtained from this review?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

8. Did the inspector collect adequate evidence and documentation in accordance with state procedures given the nature of the inspectional findings?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

9. Did the inspector verify correction of deficiencies identified during the previous state inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

10. Did the inspector act in a professional manner and demonstrate proper sanitary practices during the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II.A. INSPECTIONAL OBSERVATIONS AND PERFORMANCE FOR "HACCP REGULATED" FACILITIES

Note to Auditor: These four questions only apply to firms subject to HACCP regulations. These four questions should be left blank for firms not subject to HACCP regulations.

1. Did the inspector use the "Fish and Fishery Products Hazards and Controls Guide" or the "Juice HACCP Hazards and Controls Guide," as appropriate, to identify and evaluate the hazards associated with the product and process?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. Did the inspector assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

3. Did the inspector review the firm's HACCP plan (or necessary process controls in the absence of a HACCP Plan) and applicable monitoring, verification, and corrective action records, including those related to sanitation?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II.A. INSPECTIONAL OBSERVATIONS AND PERFORMANCE FOR “HACCP REGULATED” FACILITIES

4. Did the inspector recognize deficiencies in the firm’s monitoring and sanitation procedures through in-plant observations?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION

1. Did the inspector identify himself/herself and make appropriate introductions, which include explaining the purpose and scope of the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. Did the inspector use suitable interviewing techniques?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

3. Did the inspector explain findings clearly and adequately throughout the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION (Continued)

4. Did the inspector alert the firm's appropriate management when an immediate corrective action was necessary?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

5. Did the inspector answer questions and provide information in an appropriate manner?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

6. Did the inspector write their findings accurately, clearly and concisely on the state document/form left with the firm?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

**IV. INSPECTIONAL OBSERVATIONS AND PERFORMANCE
FOR PC LIMITED SCOPE AND MODIFIED SCOPE AUDITS**

1. Did the inspector properly evaluate the good manufacturing requirements (117 Subparts A, B, and F, or equivalent state regulation)? This question applies to all audits performed including food, seafood and juice. It cannot be left blank.

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. Did the inspector conduct a broad-based assessment of the preventative controls program where necessary? This question applies to limited scope PC inspections or if it is a qualified facility that attested under 21 CFR 117.201(a)(2)(i). If the question does not apply, select Not Applicable.

Acceptable Needs Improvement Not Applicable

COMMENTS *(required for Needs Improvement)*

3. Did the inspector evaluate if the facility was in compliance with its attestation? Only applies when a firm self-attests under 21 CFR 117.201(a)(2)(i) or (ii). If the question does not apply, select Not Applicable.

Acceptable Needs Improvement Not Applicable

COMMENTS *(required for Needs Improvement)*

4. Did the inspector properly evaluate the implementation of time/temperature controls? Only answer if the facility is a warehouse solely engaged in the storage of unexposed packaged food that requires refrigeration for safety. If the question does not apply, select Not Applicable.

Acceptable Needs Improvement Not Applicable

COMMENTS *(required for Needs Improvement)*

ADDITIONAL COMMENTS

SIGNATURE OF AUDITOR

DATE

NOTE: EVERY ITEM MARKED "NEEDS IMPROVEMENT" MUST BE ACCOMPANIED BY AN EXPLANATION OF WHY THE ITEM WAS MARKED AS NEEDING IMPROVEMENT.

Special Instructions:

Section II.A. INSPECTIONAL OBSERVATIONS AND PERFORMANCE FOR "HACCP-REGULATED" FACILITIES

- Answer this section if the establishment is subject to Seafood or Juice HACCP regulations. These four questions should be left blank for firms not subject to HACCP regulations.

Section IV. INSPECTIONAL OBSERVATIONS AND PERFORMANCE FOR PC LIMITED SCOPE AND MODIFIED

SCOPE AUDITS

- Question one applies to ALL audits performed including food, seafood and juice and should be answered for every audit.
- Questions 2, 3, and 4 should be marked Not Applicable when a firm is not subject to the regulation.

Overall Rating:

If three or less items are marked "needs improvement," the overall rating is "acceptable." If four or more items are marked "needs improvement," the overall rating is "needs improvement." The overall rating must be marked in the space provided in the header on the first page.

All contract inspectors who receive an overall audit score of "needs improvement" shall receive remedial training in deficient areas or as agreed upon by the state and FDA Division prior to resuming contract inspection duties.

DRAFT

Chem LFFM Human & Animal Food State Surveillance Data Entry Instructions

Quarterly Surveillance Data Spreadsheet

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| At the Beginning of the Budget Period | 1 |
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At the Beginning of the Budget Period

1. Enter the current budget period's activation workgroup "LFFM C-HAF Product Testing Track Quarterly Reporting"
2. Download the surveillance template from Lab Data Entry portion of the workgroup.
 - a. Click "Enter Lab Data"
 - b. Click "Get Blank Data Spreadsheet Template"
 - c. Open with Excel

The screenshot shows the 'Enter Lab Data' button highlighted in a red box. Below it, the 'Get Blank Data Spreadsheet Template' button is also highlighted in a red box. The interface includes a navigation menu at the top with options like 'Manage Event', 'Event Home', 'Lab Data Entry', 'New SitRep Entry', 'View SitRep', 'Documents', 'Meetings', 'Communications', 'More Apps', and 'Admin'. The main content area displays 'Contact Information' for Kirsten Hirneisen, 'Sample Data Entered' (YES) by Tara Doran on Dec 7, 2020, and 'Supporting File Uploads' (No current uploads). A right-hand sidebar lists 'Activation Group Apps' such as 'MANAGE EVENT', 'EVENT HOME', 'LAB DATA ENTRY', 'New SitRep Entry', 'View SitRep', 'Documents', 'Meetings', 'Communications', 'Calendars', 'FAQs', 'Forums', 'Links', 'Members', 'Photos', 'Polls', 'Scheduler', 'SecureSend', 'Teams', 'Video Gallery', and 'Admin'. A file dialog box is open over the 'Get Blank Data Spreadsheet Template' button, showing the file 'Data Entry Template Micro HF and AF LFFM Year 1 9.xlsx' (90.7 KB) from 'https://s3-fips-us-gov-west-1.amazonaws.com'. The dialog asks 'What should Firefox do with this file?' with options: 'Open with Excel (default)', 'Save File', and 'Do this automatically for files like this from now on.' The 'Open with Excel (default)' option is selected.

3. Save the template in your files without changing any rows, columns or cells in the spreadsheet. You can enable editing. This will serve as the document that you will use to track your surveillance data.

Throughout the Budget Period

4. Record surveillance data throughout the budget period in the spreadsheet without changing anything about the template including column headers, sizes, blank areas, row heights, etc.

a. Columns A-P are required to be filled out for each sample (see exception for column G, below). If you do not have the information for those columns you can write “unknown”.

i. Recording ‘unknown’ is **not appropriate** for all fields.

1. For example – If an expiration date is not listed on the label, it is okay to record ‘unknown’ in this field. It is not appropriate to record ‘unknown’ for manufacturer/brand, or collection date, or other key identifying information about the sample.

ii. For human food samples, record “N/A – Human Food” in column F, and then column G can be left blank

b. **SPECIAL NOTES – IMPORTANT:**

i. Commodity Category (Assigned) – Column E – this MUST be the commodity category selected for your sample-product must match the assigned commodity/hazard pair category that was on your approved Sampling Plan

1. Special note – if your laboratory participated in the FDA 3rd party (IEH) cereal assignment, record your samples against the category “RTE

ii. Country of Origin – this is the country of the manufacturer/processor (responsible firm). Examples:

1. Enoki mushrooms, says ‘distributed by’ a US company, product of China – record China as country of origin

2. Cashews, says ‘packed/processed by’ a US company, and on label lists ‘contains cashews from vietnam, brazil, ivory coast’ – record US as country

3. Identity of firm that produced the product unclear – record ‘unknown’ for country of origin

iii. Collecting Entity – Column M

1. If collected by laboratory analysts, write “Laboratory”

2. If collected by a regulatory program, write the Agency name and the program name – E.g., State Department of Agriculture, Food Safety Division

3. Special note – if your laboratory participated in the FDA 3rd party (IEH) cereal assignment, enter “IEH – FDA 3rd Party Cereal Assignment”

iv. Analyte fields:

1. Screen Result values:

a. CRO – Cannot Rule Out – please select if a screen was performed and the result was detected

b. ND – Not Detected – please select if a screen was performed and the result was not detected

c. N/A – Not Performed – please select if you were testing for the analyte, but did not perform a screening test

2. Confirmatory Result values:

a. Salmonella spp. (or other analyte) Found – please select if a confirmatory test was performed and the result was detected

b. No Salmonella spp. (or other analyte) Found – please select if a confirmatory test was performed and the result was not detected

c. N/A – Not Performed – please select if you were testing for the analyte, but did not perform a confirmatory test (e.g., because the screen was not detected)

3. Final Result values

a. Salmonella spp. (or other analyte) Found – please select if the confirmatory test showed that the target analyte was detected

b. Negative – please select if a screen test showed the target analyte was not detected (no confirmatory test performed), or a confirmatory test

v. Salmonella Serotype – Column U – for poultry feed samples positive for *Salmonella* only, please enter the Salmonella serotype

vi. Comments – Column BG – for positive samples, please include any details re: state action taken on the sample results – embargo, recall, consumer advisory, etc.

c. Leave testing columns **blank** if you did not perform that testing.

i. Do not put N/A in columns/fields for analytes you didn’t test for. For example – Tomatoes analyzed for Salmonella: N/A in Confirmatory test has meaning (confirmatory test was not performed, screen was Not Detected); do not put N/A in the Listeria, Campy, Cyclo analysis fields – leave them blank.

d. Leave Turn-Around-Time columns **blank** – we will fill them out later using a formula (NETWORKDAYS - number of work days between the time

e. Please check all dates for typos (correct budget periods) before submitting

5. **FDA ORS will coordinate when your surveillance data should be uploaded to the data entry section. This will happen on a quarterly basis and**

Submitting your Data

How the FERN Activation Data Entry Module Works

When you upload a new spreadsheet (dataset), the system looks at the Sample ID field and compares it to the data already in the system that your lab

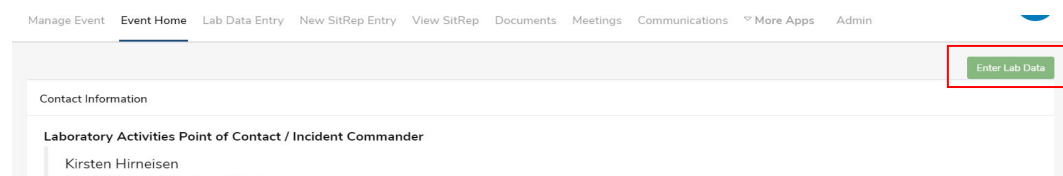
- If the sample ID is new, then it adds the new record
- If the sample ID is the same as another sample previously submitted, then it updates the data for that sample (overwrites it)

When submitting data in Q2-4, we recommend that you only submit the new quarter’s samples (so you are only submitting new sample IDs to the

- If you opt to have a single spreadsheet (including all samples from the budget period) that you upload every quarter, please be aware that every

When you are ready to upload your surveillance data to the activation workgroup follow these instructions:

6. Go the activation workgroup and select “Enter Lab Data”



Email: Kirsten.Hirneisen@tda.nns.gov
Phone: 949-608-4461

7. Click on "Get Blank Data Spreadsheet Template"

Manage Lab Data: Virginia Division of Consolidated Laboratory Services

[Get Blank Data Spreadsheet Template](#)

Sample Data Entered Last Entered By

NO [Enter Lab Sample Data](#) [Upload Supporting Files](#) [Get Sample Data Spreadsheet Report](#)

Supporting File Uploads

No current uploads

8. Open it with Microsoft Excel

9. Click on Enable Editing

10. Without changing anything about the blank data spreadsheet, copy and paste just the surveillance data from the template you had saved in your records. It works best if you only highlight the entire section of data instead of selecting entire rows. NOTE: You can attempt to skip steps 2-5 and just upload the spreadsheet you have in your files, but we find that starting fresh with a new template prevents errors.

11. Once your quarterly data is populated into the blank data spreadsheet template, save it to your desktop or in your files, keeping the same name as what was given by the system (it may save as "copy of..." which is fine)

12. Click "Enter Lab Sample Data"

Manage Lab Data: Virginia Division of Consolidated Laboratory Services

[Get Blank Data Spreadsheet Template](#)

Sample Data Entered Last Entered By

NO [Enter Lab Sample Data](#) [Upload Supporting Files](#) [Get Sample Data Spreadsheet Report](#)

Supporting File Uploads

No current uploads

13. Click "Upload Spreadsheet"

Submit Lab Data

REMEMBER TO CLICK THE "SAVE DATA" BUTTON ABOVE THE GRID BEFORE YOU LEAVE THIS PAGE OR ANY UPDATES WILL BE LOST.

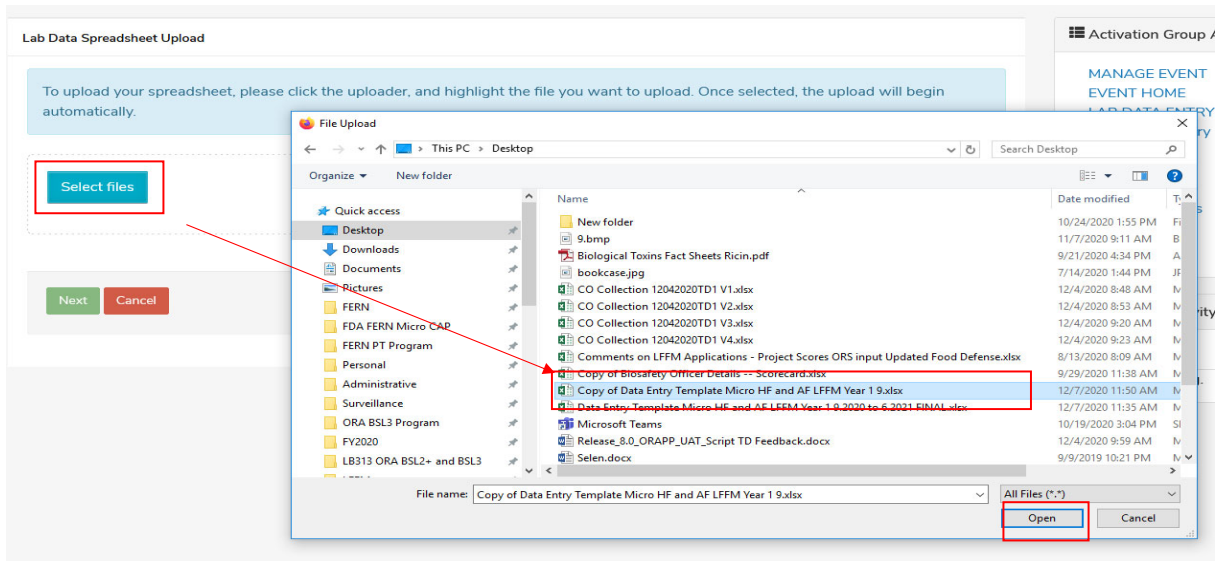
Would you like to upload a spreadsheet template?

[Upload Spreadsheet](#)

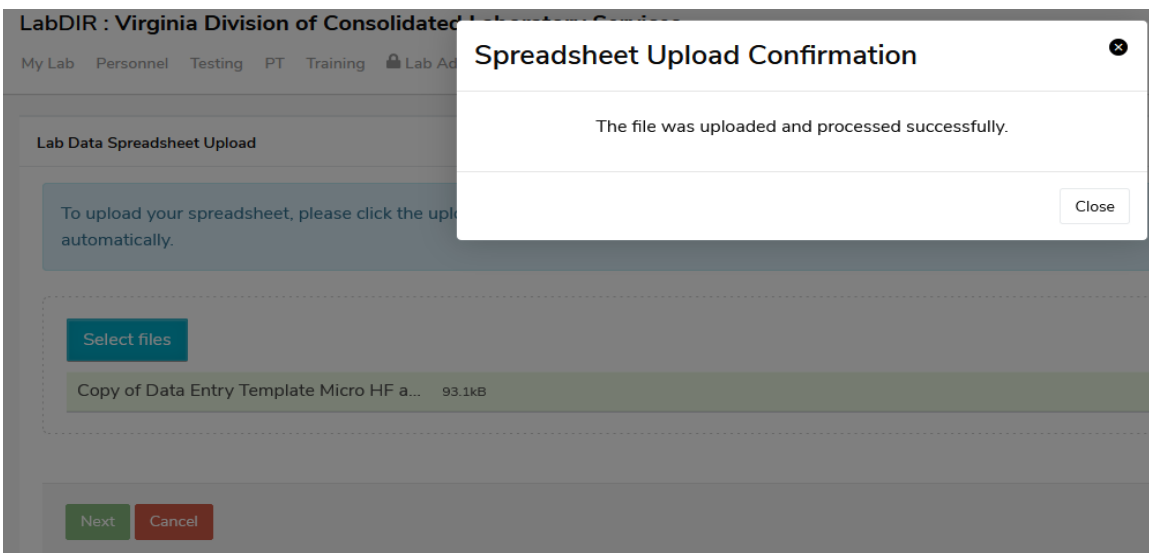
[Save Data](#) [Add Row](#) [Delete Rows](#)

| | Sample Number (ID) | Product Description | Manufacturer/Brand | Product Code | Product Expiration Date | Collecting Entity | Date Collecte |
|---|--------------------|---------------------|--------------------|--------------|-------------------------|-------------------|---------------|
| 1 | | | | | | | |

14. Click "Select Files". Find the document you just saved and click "Open"



15. When the document is done processing - Click Next. The system will check to see if your spreadsheet matches the data entry requirements. It should give you a successful confirmation. If you have made changes to the spreadsheet you will get an error message.



16. The data you copied should show in the data entry module on the screen. Check to be sure all your data was uploaded and then click "save data". If you forget to click save you will lose your data.

Submit Lab Data

REMEMBER TO CLICK THE "SAVE DATA" BUTTON ABOVE THE GRID BEFORE YOU LEAVE THIS PAGE OR ANY UPDATES WILL BE LOST.

Would you like to upload a spreadsheet template?

Upload Spreadsheet

Save Data

Add Row

Delete Rows

| | Lab Name | State | Sample Number (ID) | LFFM Track |
|---|-----------|--|--------------------|----------------|
| 1 | Fake Data | 7065 - Alaska State Department of Environmental Conservation | AK | Micro Human Fo |
| 2 | | | | |

17. After your data is saved you can add rows to manually add more data, delete rows that had errors etc.

Troubleshooting:

The majority of data upload errors are because of changes to the spreadsheet template, blank rows, formatting changes, etc. If you receive an error message, please follow the instructions exactly and only copy and paste the cells with data into the downloaded template without selecting entire rows and columns. If you still experience issues reach out to your FDA technical lead(s).

Important:

This workgroup is used to track your state collected and state analyzed surveillance data. Any other data for other tracks or associated with FDA assignments or actual activations should be entered into the activations set up for that purpose and should not be double-entered in this activation workgroup. If you have questions reach out to your FDA technical lead(s).

- For the current budget period - if your laboratory participated in the FDA 3rd party (IEH) cereal assignment, record your samples against the category "RTE packaged/boxed cereals & granolas (not bulk)", even if it was not on your approved sampling plan. In Comments (very last field), record "FDA 3rd Party Cereal Assignment". Record samples that were analyzed during the LFFM budget period/reporting period.
- For current budget period - If your lab chose to use LFFM funds to do Cronobacter testing for the recent event in Infant Formula, please report all LFFM funded Cronobacter samples. As there is no column for Cronobacter in the reporting template, please use the "Other Analyte" Column and write in "Cronobacter sakazakii" (NOTE: This is not an option in the drop down menu and must be typed in).

Change History

- 1/27/22 – clarified that calculation of turnaround time is done based on net work days (including federal holidays)
- 2/8/22 – added examples of how to interpret and record Country of Origin
- 4/4/22 – added information on how to report Cronobacter testing

Micro LFFM Human & Animal Food State Surveillance Data Entry Instructions

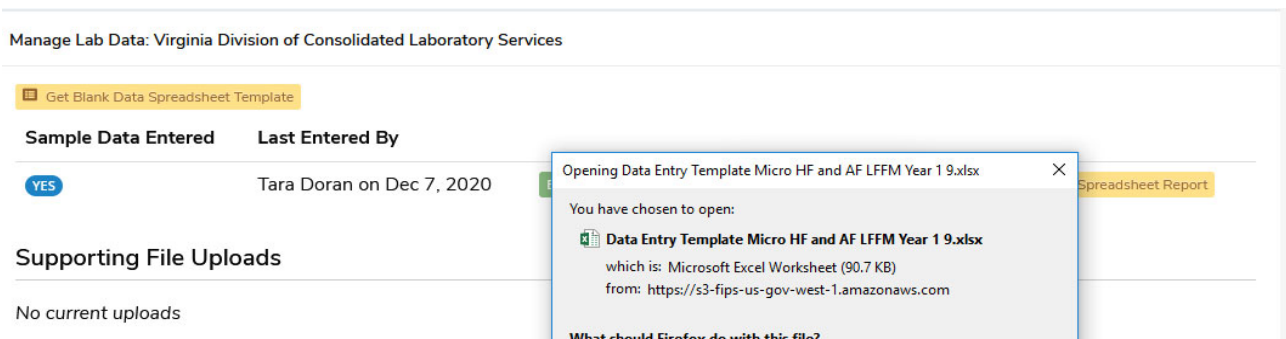
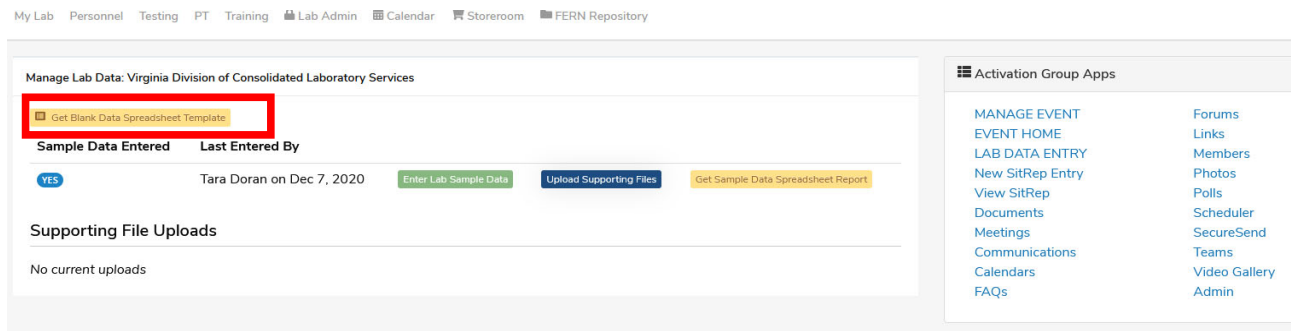
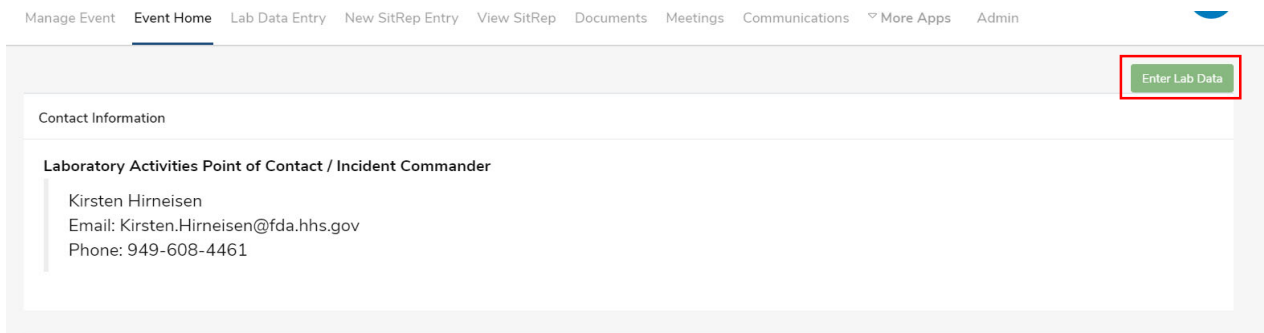
Quarterly Surveillance Data Spreadsheet

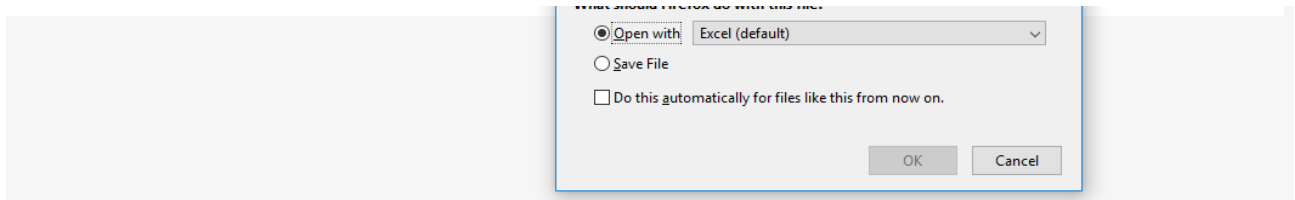
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At the Beginning of the Budget Period

1. Enter the activation workgroup “LFFM M-HAF Product Testing Track Quarterly Reporting”
2. Download the surveillance template from Lab Data Entry portion of the workgroup.
 - a. Click “Enter Lab Data”
 - b. Click “Get Blank Data Spreadsheet Template”
 - c. Open with Excel





3. Save the template in your files without changing any rows, columns or cells in the spreadsheet. You can enable editing. This will serve as the document that you will use to track your surveillance data.

Throughout the Budget Period

4. Record surveillance data throughout the budget period in the spreadsheet without changing anything about the template including column headers, sizes, blank areas, row heights, etc.

a. Columns A-P are required to be filled out for each sample (see exception for column G, below). If you do not have the information for those columns you can write “unknown”.

i. Recording ‘unknown’ is **not appropriate** for all fields.

1. For example – If an expiration date is not listed on the label, it is okay to record ‘unknown’ in this field. It is not appropriate to record ‘unknown’ for manufacturer/brand, or collection date, or other key identifying information about the sample.

ii. For human food samples, record “N/A – Human Food” in column F, and then column G can be left blank

b. **SPECIAL NOTES – IMPORTANT:**

i. If your lab chose to use LFFM funds to do Cronobacter testing for the recent event in Infant Formula, please report all LFFM funded Cronobacter samples. As there is no column for Cronobacter in the reporting template, please use the "Other Analyte" Column and write in "Cronobacter sakazakii" (NOTE: This is not an option in the drop down menu and must be typed in).

ii. Commodity Category (Assigned) – Column E – this MUST be the commodity category selected for your sample-product must match the assigned commodity/hazard pair category that was on your approved Sampling Plan

1. Special note – if your laboratory participated in the FDA 3rd party (IEH) cereal assignment, record your samples against the category “RTE packaged/boxed cereals & granolas (not bulk)”, even if it was not on your current budget period's approved sampling plan. In Comments (very last field), record “FDA 3rd Party Cereal Assignment”. Record samples that were analyzed during the LFFM budget period/reporting period.

iii. Country of Origin – this it is the country of the manufacturer/processor (responsible firm).

Examples:

1. Enoki mushrooms, says ‘distributed by’ a US company, product of China – record China as country of origin

2. Cashews, says ‘packed/processed by’ a US company, and on label lists ‘contains cashews from vietnam, brazil, ivory coast’ – record US as country of origin

3. Identity of firm that produced the product unclear – record ‘unknown’ for country of origin

iv. Collecting Entity – Column M

1. If collected by laboratory analysts, write “Laboratory”

2. If collected by a regulatory program, write the Agency name and the program name – E.g., State Department of Agriculture, Food Safety Division

3. Special note – if your laboratory participated in the FDA 3rd party (IEH) cereal assignment, enter “IEH – FDA 3rd Party Cereal Assignment”

v. Analyte fields: Screen, Confirmatory, Final

1. Screen Result values:

- a. CRO – Cannot Rule Out – please select if a screen was performed and the result was detected
- b. ND – Not Detected – please select if a screen was performed and the result was not detected
- c. N/A – Not Performed – please select if you were testing for the analyte, but did not perform a screening test

2. Confirmatory Result values:

- a. Salmonella spp. (or other analyte) Found – please select if a confirmatory test was performed and the result was detected
- b. No Salmonella spp. (or other analyte) Found – please select if a confirmatory test was performed and the result was not detected
- c. N/A – Not Performed – please select if you were testing for the analyte, but did not perform a confirmatory test (e.g., because the screen was not detected)

3. Final Result values

- a. Salmonella spp. (or other analyte) Found – please select if the confirmatory test showed that the target analyte was detected
- b. Negative – please select if a screen test showed the target analyte was not detected (no confirmatory test performed), or a confirmatory test showed the target analyte was not detected.

vi. Salmonella Serotype – Column U – for poultry feed samples positive for *Salmonella* only, please enter the Salmonella serotype

vii. Comments – Column BG – for positive samples, please include any details re: state action taken on the sample results – embargo, recall, consumer advisory, etc.

c. Leave testing columns **blank** if you did not perform that testing.

i. Do not put N/A in columns/fields for analytes you didn’t test for. For example – Tomatoes analyzed for Salmonella: N/A in Confirmatory test has meaning (confirmatory test was not performed, screen was Not Detected); do not put N/A in the Listeria, Campy, Cyclo analysis fields – leave them blank.

d. Leave Turn-Around-Time columns **blank** – we will fill them out later using a formula (NETWORKDAYS - number of work days between the time you finished analysis and the time you started the analysis, will also remove federal holidays from the calculation).

e. Please check all dates for typos (correct budget periods) before submitting

5. FDA ORS will coordinate when your surveillance data should be uploaded to the data entry section. This will happen on a quarterly basis and should not be done until prompted. **NOTE: Any sample testing resulting in a CRO or confirmed positive must be communicated immediately to the LFFM Inbox and HAF Division Inbox and cannot wait until the quarterly upload.**

Submitting your Data

How the FERN Activation Data Entry Module Works

When you upload a new spreadsheet (dataset), the system looks at the Sample ID field and compares it to the data already in the system that your lab submitted.

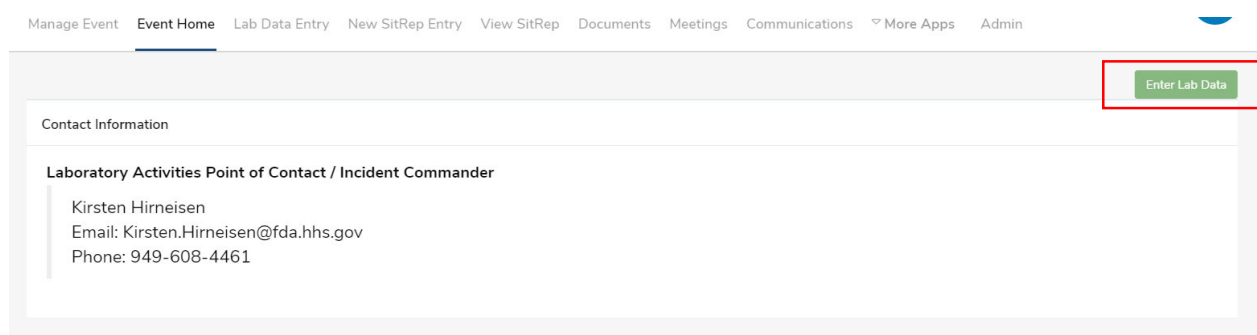
- If the sample ID is new, then it adds the new record
- If the sample ID is the same as another sample previously submitted, then it updates the data for that sample (overwrites it)

When submitting data in Q2-4, we recommend that you only submit the new quarter's samples (so you are only submitting new sample IDs to the system). However, we don't want to be burdensome, so if it is easier for you to have a single spreadsheet with the entire Budget period's samples and upload it at each quarter, that is acceptable.

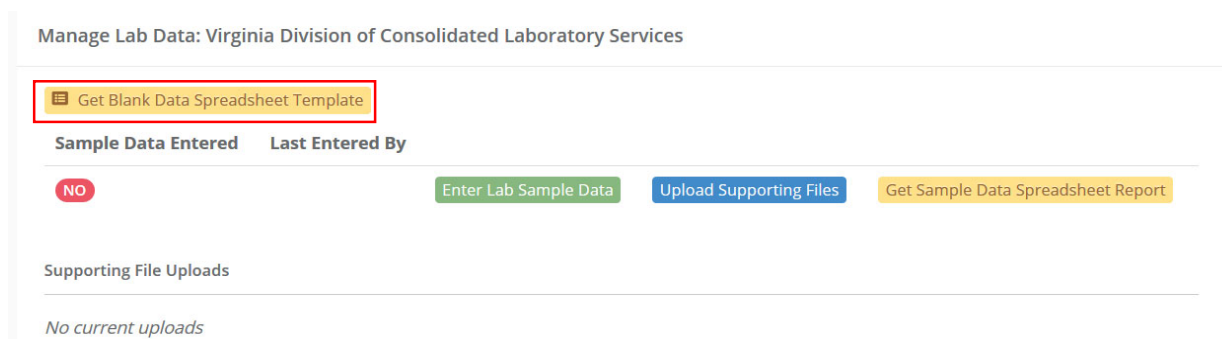
- If you opt to have a single spreadsheet (including all samples from the budget period) that you upload every quarter, please be aware that every time you submit data, you are overwriting data from a prior quarter (same sample IDs). This becomes important if ORS asked you to update or fix data elements during a prior quarters' data review. You **must** make sure those edits are reflected in both the FERNIlab.org activation portal and your locally saved data spreadsheet, otherwise when you submit data in a future quarter, the fixed data elements will revert back to their prior state and need to be cleaned/updated again.

When you are ready to upload your surveillance data to the activation workgroup follow these instructions:

6. Go the activation workgroup and select "Enter Lab Data"



7. Click on "Get Blank Data Spreadsheet Template"



8. Open it with Microsoft Excel

9. Click on Enable Editing

10. Without changing anything about the blank data spreadsheet, copy and paste just the surveillance data from the template you had saved in your records. It works best if you only highlight the entire section of data instead of selecting entire rows. NOTE: You can attempt to skip steps 2-5 and just upload the spreadsheet you have in your files, but we find that starting fresh with a new template prevents errors.

11. Once your quarterly data is populated into the blank data spreadsheet template, save it to your desktop or in your files, keeping the same name as what was given by the system (it may save as "copy of..." which is fine)

12. Click "Enter Lab Sample Data"

Manage Lab Data: Virginia Division of Consolidated Laboratory Services

[Get Blank Data Spreadsheet Template](#)

Sample Data Entered Last Entered By

NO

[Enter Lab Sample Data](#)

[Upload Supporting Files](#)

[Get Sample Data Spreadsheet Report](#)

Supporting File Uploads

No current uploads

13. Click "Upload Spreadsheet"

Submit Lab Data

REMEMBER TO CLICK THE "SAVE DATA" BUTTON ABOVE THE GRID BEFORE YOU LEAVE THIS PAGE OR ANY UPDATES WILL BE LOST.

Would you like to upload a spreadsheet template?

[Upload Spreadsheet](#)

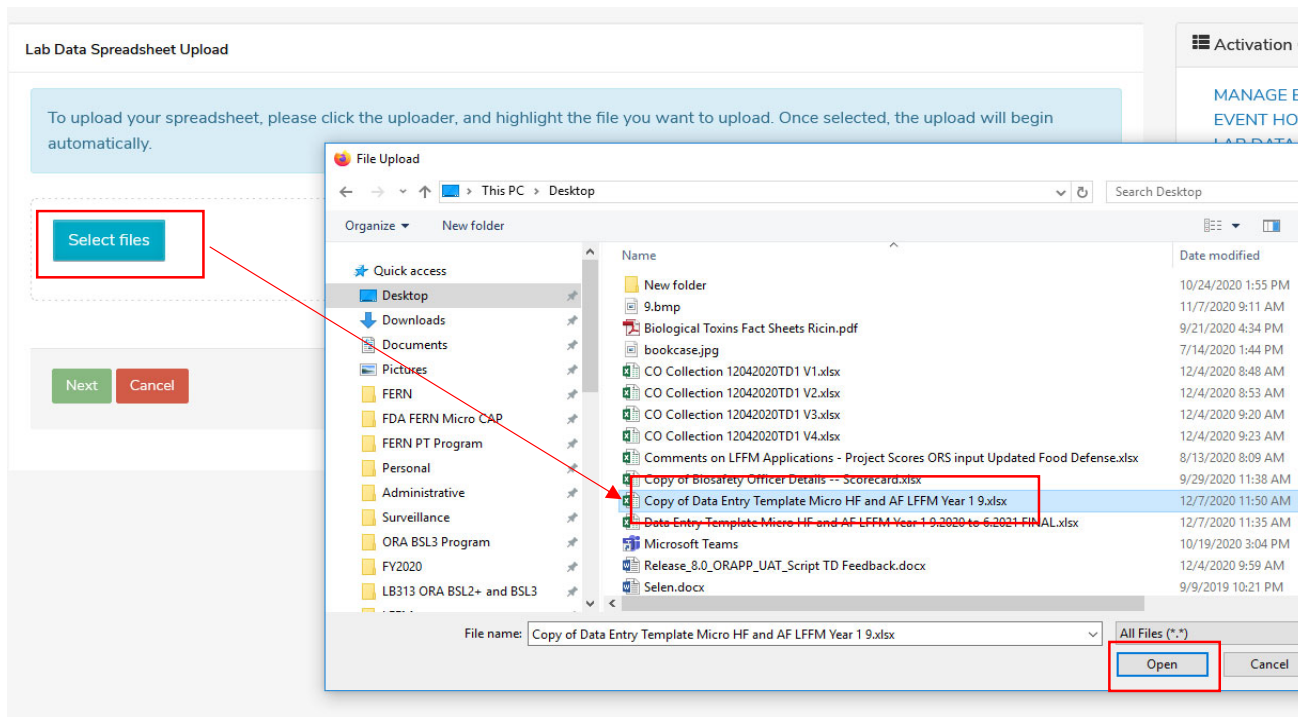
[Save Data](#)

[Add Row](#)

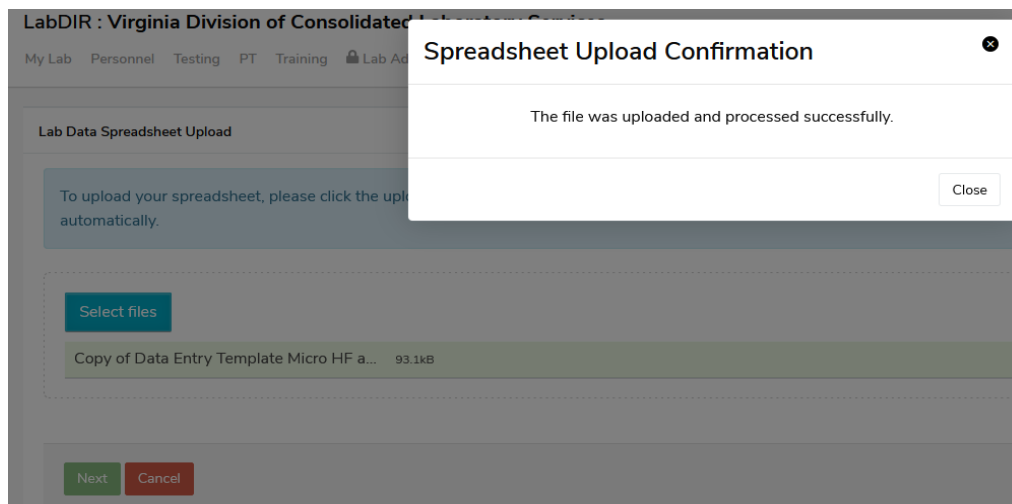
[Delete Rows](#)

| | Lab Name | State | Sample Number (ID) | LFFM Track |
|---|-----------|--|--------------------|----------------|
| 1 | Fake Data | 7065 - Alaska State Department of Environmental Conservation | AK | Micro Human Fo |
| 2 | | | | |

14. Click "Select Files". Find the document you just saved and click "Open"



15. When the document is done processing - Click Next. The system will check to see if your spreadsheet match



16. The data you copied should show in the data entry module on the screen. Check to be sure all your data was uploaded and then click "save data". If you forget to click save you will lose your data.

Submit Lab Data

REMEMBER TO CLICK THE "SAVE DATA" BUTTON ABOVE THE GRID BEFORE YOU LEAVE THIS PAGE OR ANY UPDATES WILL BE LOST.

Would you like to upload a spreadsheet template?

Upload Spreadsheet

Save Data Add Row Delete Rows

| | Sample Number (ID) | Product Description | Manufacturer/Brand | Product Code | Product Expiration Date | Collecting Entity | Date Collected |
|---|--------------------|---------------------|--------------------|--------------|-------------------------|-------------------|----------------|
| 1 | | | | | | | |

17. After your data is saved you can add rows to manually add more data, delete rows that had errors etc.

Troubleshooting:

The majority of data upload errors are because of changes to the spreadsheet template, blank rows, formatting changes, etc. If you receive an error message, please follow the instructions exactly and only copy and paste the cells with data into the downloaded template without selecting entire rows and columns. If you still experience issues reach out to your FDA technical lead(s).

Important:

This workgroup is used to track your state collected and state analyzed surveillance data. Any other data for other tracks or associated with FDA assignments or actual activations should be entered into the activations set up for that purpose and should not be double-entered in this activation workgroup. If you have questions reach out to your FDA technical lead(s).

- For the current budget period - if your laboratory participated in the FDA 3rd party (IEH) cereal assignment, record your samples against the category "RTE packaged/boxed cereals & granolas (not bulk)", even if it was not on your current budget period's approved sampling plan. In Comments (very last field), record "FDA 3rd Party Cereal Assignment". Record samples that were analyzed during the LFFM budget period/reporting period (7/1 or later).
- For the current budget period - If your lab chose to use LFFM funds to do Cronobacter testing for the recent event in Infant Formula, please report all LFFM funded Cronobacter samples. As there is no column for Cronobacter in the reporting template, please use the "Other Analyte" Column and write in "Cronobacter sakazakii" (NOTE: This is not an option in the drop down menu and must be typed in).

Change History

- 1/27/22 – clarified that calculation of turnaround time is done based on net work days (including federal holidays)
- 2/8/22 – added examples of how to interpret and record Country of Origin
- 4/4/22 – added information on how to report Cronobacter testing

Contents

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 - Animal Food Chemistry Track (C-AF) sampling projects/options
 - Human Food Chemistry Track (C-HF) sampling projects/options
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I. Documents included in LFFM the Sample and Activity Plan Proposal Request

The following documents are available to LFFM grantees on the Food Emergency Response Network (FERN) Portal (www.fernlab.org) with the LFFM Sample and Activity Plan Proposal Template (this spreadsheet) to assist in completing the LFFM Sample and Activity Plan Proposal (SAPP). References to these documents within these instructions are color coded, to help make it easy to identify which documents are being referenced.

- **LFFM Sample and Activity Plan Options by Track spreadsheet** – list of currently offered activities or sampling priorities for each Track
- **SRP-Lab Agreement Template** – word document example/template for the SRP-Lab Agreement, required for labs in Human and Animal Food Product Testing Tracks
- **Supplemental Instructions Documents** – some sampling priorities (e.g., Total Diet Study [TDS]) have an instructions document providing additional detail about the project (desired collections and testing). These are also posted in the FERN Portal.

II. Next Budget Period Proposal Submission

Labs are to submit, the following documents to: OM PO (Laurie Keppley), OP Project Manager (PM) and ORS LFFM Technical Program Manager (Lauren Yeung)

- Sample and Activity Plan Proposal (this spreadsheet) completed for all tracks you wish to participate in for the next budget period (note some tracks without activity or sampling options are not in the spreadsheet). Note that submitting this form does not constitute an official request for funding, grantees must request funds for these tracks via the RPPR.
- SRP-Lab Agreement (word document) – only for labs in M-HF, M-AF, C-HF, or C-AF Tracks; this agreement covers all commodity-hazard pairs for the M-HF, M-AF, C-HF, or C-AF Tracks included in this spreadsheet as the Sample and Activity Plan Proposal.

III. Completing the LFFM Sample and Project Plan Proposal (this spreadsheet).

A. Coversheet

Please provide the requested administrative information, including the appropriate contacts to receive communications about your LFFM Sample and Activity Plan proposal for the next budget period. ORS and OP will communicate with these contacts during the LFFM sampling plan/project negotiation phase.

Please indicate which Tracks your lab is proposing work for in the next budget period. With the following exceptions, laboratories must ONLY complete tabs (submit proposals) for tracks they were approved AND funded for in LFFM for the current budget period.

- The LFFM program will not be picking up any new labs to participate in the Food Defense, Human Food Testing, nor the Animal Food Testing tracks for the next budget period, with the following exception: Laboratories “Approved” and “Unfunded” for the M-AF Track in previous two budget periods may submit an M-AF Track proposal for the next budget period. This proposal can only include NARMS sampling work and cannot include state-proposed commodity-hazard pairs, or any other FDA-proposed commodity-hazard pairs offered for M-AF in the next budget period.
- LFFM grantees can propose a Micro or Chem Capability/Capacity Development Track project or Method Development/Validation Track project if they are “approved” for the track, regardless of whether you were funded in the current budget period.

Some Tracks do not have tabs in the spreadsheet because there are no projects to select from. This includes: SP-IT (ORA DX), SP-Sample Collection, Rad Capability/Capacity Development (not open this budget period). If you are approved for the SP-IT and SP-Sample Collection tabs, you can include those in your RPPR budget and continuation application in eRA commons. Your funding tier for SP-Sample Collection should match the funding tier for total M-HF, M-AF, C-HF, C-AF work proposed for the next budget period.

| Track | Sample Load | Number of Samples | Funding |
|-------|-------------|-------------------|---------|
|-------|-------------|-------------------|---------|

| | | (calculated using the sample numbers from the testing track(s) tier(s) your lab participates in – i.e., 100/250/500) | |
|-------------------|--------|--|----------|
| Sample Collection | Low | 100 – 500 | \$25,000 |
| | Medium | 501 – 1000 | \$35,000 |
| | High | >1000 | \$45,000 |

IMPORTANT NOTE: LFFM grantees cannot increase their HAF Product Testing Track, WGS Track sample tier, or SP-Sample Collection Track tier beyond what the original LFFM application was approved for; however, grantees can reduce their tier voluntarily.

B. M-HF, M-AF, C-HF, C-AF Tracks

See “LFFM Sample and Activity Plan_Options by Track.xlsx” on the FERN Portal www.fernlab.org for a listing of all sampling and activity options for LFFM Tracks (M-HF, M-AF, C-HF, C-AF, Food Defense, Capability/Capacity Development, Method Development/Validation) for the next budget period.

Laboratories are to review these sampling options, including discussions with SRP partners for M-HF, M-AF, C-HF and C-AF Tracks, to determine what sampling projects to propose for the next budget period. The LFFM Sample Guide contains many suggestions on what to consider when discussing LFFM sampling options for the next budget period with SRP partners. See *LFFM Sample Guide* section “Determining which Commodity-Hazard Pairs to Propose.”

Laboratories are to list the sampling projects they would like to pursue in the next budget period in the following tabs of this spreadsheet. All fields should be completed for each commodity-hazard pair. There are some changes to the proposal fields (compared to the previous budget period), so read the template carefully.

Considerations and guidelines for selecting commodity-hazard pairs for the next budget period

Laboratories should only propose commodity/hazard pairs for which they are already able to conduct analyses (e.g., it is not appropriate to propose work that requires use of a specific piece of equipment that will not be operational until 3-6 months into the budget period). It is permissible to propose work that requires limited work to validate/verify an existing method for a new matrix. No new major method validation or method development work will be allowed for proposed commodity/hazard pairs. If questions arise over effort of work for minor vs. major development work please reach out to LFFM Human and Animal Food Track Contacts for clarification.

Laboratories must use validated methods that are equivalent to official methods (see definition below). If methods used for LFFM Product Testing Tracks are not on the laboratory's scope of accreditation, validation data may be requested by ORS Technical Leads. All matrices must be validated or verified to be run with the intended method. Matrix verifications may also be requested by ORS Technical Leads.

Equivalent to Official Methods: This phrase is used to describe the deliberative process used by ORS to ensure methods used by LFFM laboratories for LFFM work is technically sound and fit for use. Items considered include:

- Is the method fit for purpose (appropriate for the commodity/hazard pair; the purpose/intent of the sampling effort,
- Is the method an official method (FDA, AOAC, etc.); or if it is a modified official method or a method from another source (in-house, etc.), is it validated/verified
- Is the method validated for the matrix; are matrix spikes or inclusion of Standard Reference Material/Certified Reference Material (SRM/CRM) needed)
- If applicable, MLOD and MLOQ are available and appropriate for the commodity/hazard pair
- Is the method under ISO scope; if not, is it validated/verified in the lab?

Laboratories should be proactive in identifying back-up commodity-hazard pairs in the event they are asked to replace or reduce the numbers for a commodity-hazard pair included in their proposal. Back-up commodity-hazard pairs can be noted in the M-HF, M-AF, C-HF, and C-AF tabs, columns F and G, respectively.

Although we are asking laboratories to submit a sampling plan that represents the entire sample load for the budget period (aligned with funding level; 100, 250, 500), requests to reallocate the sampling plan are allowed, especially to accommodate high priority national outbreak or emergency response testing priorities (see LFFM Sample Guide on the FERN Portal www.fernlab.org for information on how to request reallocation).

LFFM laboratories and state regulatory programs can propose commodity-hazard pairs outside those included on the “LFFM Sample and Activity Plan_Options by Track.xlsx” document, available on the FERN Portal www.fernlab.org. Please be aware that state-proposed commodity-hazard pairs may be considered lower priority or not recommended at all for LFFM work. State-proposed commodity-hazard pairs that are identified as low priority during the review process may still be approved with additional stipulations.

Items to keep in mind when considering state-proposed commodity-hazard pairs include:

- The summary of the purpose and public health need will be critical for the FDA to evaluate if the project aligns with the goals of the cooperative agreement. Not all hazard/commodity pairs will be approved.
- Depending on the justification, state-proposed commodity-hazard pairs could be approved on sample plans even if they are not of high priority to the FDA for food safety reasons.
- FDA may not have the capacity to provide technical support, analytical guidance or follow-up actions for the testing performed for state-proposed commodity-hazard pairs. Before approving state-proposed commodity-hazard pairs, the lab may be asked to document that the SRP with appropriate jurisdiction for the proposed samples agrees to provide compliance support and initiate any necessary follow-up on these samples in the absence of support/coordination/assistance from FDA.
- State-proposed microbiology commodity-hazard pairs for human and animal food should include at least one pathogen, and state-proposed chemistry commodity-hazard pairs should focus on food contaminants. Food quality and indicator test methods, such as aerobic plate count and coliform count, and Standard of Identity should not be included in sample plans.
- Do not submit proposals for the following (animal food testing):
 - Proximate analysis
 - Raw pet food
 - Hemp and hemp byproducts

For a detailed list of commodity-hazard pairs provided as sampling projects and options for the next budget period under the M-HF, M-AF, C-HF, and C-AF tracks, see current guidance on the FERN Portal www.fernlab.org.

Notes and considerations for M-HF, M-AF, C-HF, and C-AF sampling projects/options for next budget period

“LFFM Sample and Activity Plan_Options by Track.xlsx” on the FERN Portal www.fernlab.org. Commodity-Hazard pair tab columns/data fields are organized into the following sections. Individual columns/fields may also have a hover over tool tips, with additional information about that field.

- Column Header/Section 1: Sample Designation
- Column Header/Section 2: Sample Numbers and Targets
- Column Header/Section 3: Regulatory Outlook
- Column Header/Section 4: Sample Collection Details
- Column Header/Section 5: Analytical Details
- Column Header/Section 6: Additional information

Notes and considerations related to Sections 1 and 2 (Sample Designation, Sample Numbers and Targets)

- Some commodities are listed several times (separate rows) with separate hazards (analytes). If desired, it is permissible for the SRP to work with the lab to collect 1 sample of sufficient size to support multiple analyses. This practice is neither encouraged nor discouraged and is intended to offer maximum flexibility to SRPs supporting LFFM testing.
 - Example: LFFM lab/SRP proposes:
 - 25 samples of poultry food for Salmonella
 - 25 samples of poultry food for mycotoxins (AFL, DON)
 - 25 samples of poultry food for macro mineral and moisture

- In this example, the SRP could collect 25 physical samples of sufficient size to support all analyses, and the sample is split at the lab and sent for the separate analyses
 - Flexibility in selecting analytes: Commodity-Hazard Pairs may be offered for multiple analytes (e.g., dietary supplements for lead, folic acid and vitamin D). Unless otherwise noted, flexibility is offered for LFFM grantees to propose collection and testing for one or more listed analytes of interest.
 - Priority will be given to labs that can test for all of the requested analytes.
 - In some cases (chemistry) a minimum number of analytes are required to participate in a sampling project, this will be listed in the "Hazard (Analyte)" field
 - Counting samples and analyses towards Sample Load
 - In "LFFM Sample and Activity Plan_Options by Track.xlsx" on the FERN Portal www.fernlab.org Commodity-Hazard pair tab, each commodity-hazard pair has a total number of requested samples (Column G) – this is the total number of samples desired/requested NATIONALLY - across all LFFM states for the budget period.
 - Your lab can propose any number of samples for the budget period that you feel is reasonable and fits with your lab and SRP capacity. We will look to combine testing efforts from multiple labs to total the requested number of samples, nationally, for the commodity-hazard pair.
 - Your lab's Sample Load is the number of samples associated with your M-HF, M-AF, C-HF, and C-AF funding tier (i.e., 100, 250, 500). This budget period, we are counting unique/discrete analyses towards the sample load instead of physical samples.
 - Each commodity-hazard pair has a # of unique analyses per sample (Column D) – This is used to determine how much each physical sample counts towards the LFFM tiered sample load for M-HF, M-AF, C-HF, or C-AF.
 - Within the following tabs of this spreadsheet, you will be asked for:
 - Number of Samples (annual) – this is the number of physical samples you propose to collect for the budget period
- § Number of Unique Analyses per Sample (this must be taken from "LFFM Sample and Activity Plan_Options by Track.xlsx" available on the FERN Portal www.fernlab.org, depending on how many of the target analytes of interest you select)
- Count Towards Sample Load (this is the [# of samples] x [# of unique analyses])
 - Example: State A proposes collecting and analyzing 100 samples of dried mushrooms for *Salmonella* and *Listeria monocytogenes*. State A is a M-HF, annual sample load/target: 250. Collecting 100 dried mushroom samples and analyzing for both pathogens counts as 200 out of a 250 sample load for the budget period.

Notes and considerations related to the SRP-Lab Agreement Template available on the FERN Portal www.fernlab.org (Regulatory Outlook)

- "Scope & Intent" and "Expectation for Regulatory Action" (Columns J, K): The SRP's agreement to follow-up on potentially violative samples (SRP-Lab Agreement Template available on the FERN Portal www.fernlab.org) applies to any commodity-hazard pairs marked "regulatory surveillance" (M-HF, C-HF) or "surveillance" (M-AF, C-AF). SRPs must have awareness of other (signals, TDS, NARMS) commodity-hazard pairs, especially if the SRP will be conducting collections.
 - **M-HF and C-HF Track**
 - Scope and intent: options consist of 'regulatory surveillance' (testing where published regulatory limits or action levels exist for the commodity-hazard pair); 'signals evaluation' (testing where these limits may not exist); and Total Diet Study.
 - The purpose of Signals Evaluation is to obtain additional information about the commodity/hazard pair, not to support immediate regulatory action on a sample-by-sample basis. Data will be received/reviewed in aggregate and may be used to inform future agency thinking. This may lead to shorter-term or longer-term follow-up including industry meetings, research, and inspections or sampling. Although the sampling is intended to be used for informational purposes at this time, findings of significant public health concern will be evaluated on a case-by-case basis for immediate follow-up.
 - **C-AF and M-AF Track**
 - Surveillance: sample collection occurs on an objective basis where there is no inspectional or other evidence of a problem with the product (IOM 4.4.10.3.48, Sample Basis)
 - "FDA or State Sample Collections" and "Will Center issue an Assignment" (Columns L, N): See the FERN Portal www.fernlab.org for FDA-assignments (FDA collected samples, FDA-issued assignments) currently offered.
 - For TDS projects, refer to the Supplemental Instructions Documents referenced in Column N, and provided on the FERN Portal www.fernlab.org
 - "Appropriate for retail collection by Lab Analysts" (Column M) – This field provides clarity regarding which commodity-hazard pairs are amenable for laboratory staff collection at retail. If laboratory staff will be collecting samples for commodity-hazard pairs marked "Regulatory Surveillance" (M-HF, C-HF) or "Surveillance" (M-AF, C-AF), the laboratory must document agreement that the SRP will support follow-up on potentially violative samples (SRP-Lab Agreement Template available on the FERN Portal www.fernlab.org).
 - "Is Center interested in tying collections to inspections done under food/feed contract or Produce CAP?" (Column O) – For some commodity-hazard pairs, there is specific interest from the Center in aligning the LFFM sampling with SRP inspection contract assignments, should the opportunity arise. For commodity-hazard pairs that say "yes", this is NOT a requirement, but rather a preference and a desire to see if aligning LFFM sampling plan and contract workplanning is possible. When proposing one of these commodity-hazard pairs, it is important to discuss whether the SRP would be willing to conduct sampling as part of an inspection contract assignment, should a contract inspection for an appropriate firm be assigned to the SRP. While the inspection itself would be reimbursed under contract, the sampling would not (the product sampling option under the contract is not active). Sampling can be supported using the LFFM Sample Collection Track (if your laboratory is approved/funded for this track) or using alternative funding sources available to the SRP where this activity is in scope.

Notes and considerations related to Sections 4 (Sample Collection Details)

- "Imported or domestic product (or both) of interest?" (Column R) – this column indicates whether domestic or imported product is of interest for sampling. An imported product is one that was manufactured by a foreign firm and is now in domestic commerce; a domestic product is one that was manufactured by a domestic firm.
- "Sample Collection Location(s)" (Column S) – Sample Collection Location is the type of facility from which the sample was collected. Column T further breaks down what percent of samples (nationally) are desired per collection location type.
 - C-AF and M-AF Collection Locations:
 - **Retail:** A facility in which commodities or complete feeds are available to the public for purchase. Examples include grocery stores, big-box stores like Walmart, and farm or agriculture supply stores like Southern States, Tractor Supply Co., Highland Feed & Seed Co., Mid Kansas Coop, etc. **Online sampling like Chewy or Amazon is not permitted.**
 - **Manufacturer:** A facility where ingredients or complete feeds are processed, manufactured and/or mixed. Examples include soybean processors, ethanol plants, feed mills, and pet food manufacturers.
 - For some commodity-hazard pairs, only Manufacturer is listed, but column T indicates that other collection locations may be considered and approved on a case-by-case basis. This is intended to allow for flexibility in sampling proposals when state inventory of manufacturing facilities is low. States should indicate their ability to collect all or portions of the proposed commodity-hazard pair at alternative locations (i.e., retail) accordingly.
 - When completing the column for "Collection Location" in this spreadsheet, please select from this list of values: Distributor, (G) Grower, (M) Manufacturer/Processor, (R) Packer/Repacker, (D) Retail – Farmer's Market, (D) Retail – Grocery, (D) Retail – Online/Internet, (D) Retail – Other, (P) Retail – Restaurant, (W) Warehouse, Other - Not Listed
 - The only options for C-AF and M-AF are "(D) Retail" and "(M) Manufacturer/Processor"
 - "Aseptic Sampling (Finished/Packaged Product or Aseptic Sampling from Larger Quantities)" (Column U) – Aseptic sampling is an important consideration for microbiological testing. Whenever possible, collect intact, unopened containers, and utilize aseptic sampling technique when necessary and appropriate.
 - See LFFM Sample Guide available on the FERN Portal www.fernlab.org, Section Sample Collection Best Practices - Sample Collection Techniques for information on sample collection techniques and aseptic sampling.
 - "What are the expectations around representative sampling?" (Column V) – When the SRP is collecting the sample, the SRP's existing procedures for sample collection should be utilized. When collecting single retail units of product, it is important to ensure that a single unit is of sufficient size to support the testing to be conducted; if a larger sample size is needed, multiple units may need to be collected for a single sample (units must be from the same lot). SRPs collecting at a manufacturer are encouraged to conduct sampling that is representative of the lot. See LFFM Sample Guide available on the FERN Portal www.fernlab.org, Section Sample Collection Best Practices - Sample Collection Techniques for information on sample collection techniques and representative sampling.

Notes and considerations related to Sections 5 (Analytical Details)

- MLOD/MLOQ minimum requirements (Chem) – Column Z – because flexibility in use of equivalent methods is offered, this field indicates minimum method limit of detection and limit of quantitation that must be met for any method used in this commodity-hazard pair.
- Reference material (Chem) – Column AA – Consistent with past training on analytical worksheet packages given to C-HF and C-AF labs by ORS Track Leads, the expectation is that all methods utilize a suitable reference material (i.e., the matrix is similar to the samples being tested and the reference materials have the target analyte(s) at levels reasonable for the testing). Reference materials may be an SRM/CRM or other control material, such as appropriately evaluated PT samples (AAFCO, FAPAS, etc.). For some commodity-hazard pairs, a specific SRM/CRM material is recommended. For some commodity-hazard pairs, multiple SRM/CRM or Control Materials may be necessary. Where an SRM/CRM or Control Material is not available, spike recoveries may be necessary. Reach out to ORS Track Leads if your lab wants to discuss selection of an appropriate reference material for a commodity-hazard pair.

Notes and considerations specific to Animal Food Tracks (C-AF, M-AF)

- Labs already participating in NARMS are **not eligible** for M-AF NARMS sampling projects
 - **Surveillance:** sample collection occurs on an objective basis where there is no inspectional or other evidence of a problem with the product (IOM 4.4.10.3.48, Sample Basis)
 - **Complete Feed:** A nutritionally adequate feed for animals other than man; by specific formula is compounded to be fed as the sole ration and is capable of maintaining life and/or promoting production without any additional substance being consumed except water. (AAFCO OP)
 - **Wet Pet Food:** Foods with a high moisture content. These include cans, foil trays and pouches.
 - **Sample Location:** Type of facility from which the sample was collected.
- **Retail:** A facility in which commodities or complete feeds are available to the public for purchase. Examples include grocery stores, big-box stores like Walmart, and farm or agriculture supply stores like Southern States, Tractor Supply Co., Highland Feed & Seed Co., Mid Kansas Coop, etc. **Online sampling like Chewy or Amazon is not permitted.**
- **Manufacturer:** A facility where ingredients or complete feeds are processed, manufactured and/or mixed. Examples include soybean processors, ethanol plants, feed mills, and pet food manufacturers.
- C-AF Track – macro mineral + moisture testing. FDA’s intent with these commodity-hazard pairs is aggregate data and not identifying label violations. This may represent a mutually advantageous commodity-hazard pair, as the SRP is interested in these samples for label verification and FDA is interested in aggregate data.
 - Analytical findings should be submitted quarterly. SRP can take any action deemed necessary and appropriate based on the violative finding under their own state authority. These findings do not need to be submitted to LFFM inbox, Division inbox, etc. However, in the case of complex compliance cases, labs are encouraged to contact FDA for further discussions on coordinated approaches that may include joint actions.

C. SP-MDV Track

When completing the Special Project/Method Development Method Validation (SP-MDV) Track tab in this spreadsheet, please list all MDV projects for the next budget period that your laboratory is eligible for and interested in pursuing. Your lab will not be chosen for every MDV project selected but this will allow FDA to better determine how many labs may be interested and decide which projects are priority. You will be notified which, if any, projects will be funded during the LFFM negotiations phase.

In “LFFM Sample and Activity Plan_Options by Track.xlsx” available on the FERN Portal www.fernlab.org Micro and Chem CC_MDV Projects tab, some MDV projects are listed as ‘carryover’ (see Column D) – these are projects funded in a prior budget period, organized by FDA, and were not completed on schedule. In these cases, FDA will allow LFFM grantees to carryover MDV track funds to the next budget period and allow those LFFM grantees to apply for a new MDV project in the next budget period (and receive new funds to support). LFFM grantees must indicate their intention to continue the carryover project in the SP-MDV Tab of this spreadsheet.

Other parameters:

- Labs may only be funded for 1 MDV project per budget period (micro or chem). If your lab is very interested in a second MDV project, you may select it and indicate that you are willing to conduct 2 projects for the budget period, within the \$35,000 cap for the MDV track
- If your lab is willing to continue carryover MDV project from this budget period, that must be indicated on the proposal for the next budget period – there is a column to indicate whether an MDV project is a carryover project
- State-proposed MDV projects (not on the list) **are** allowed. There is a column to indicate whether a MDV project is FDA or state proposed
- If you are willing to participate in multiple MDV projects, please indicate which is your first choice, and which are back-up choices

D. Capability/Capacity Development Track

When completing the CC Dev Track tab of this spreadsheet, please list any C/C projects for the next budget period that your laboratory is eligible for and interested in pursuing. Some projects offered under C/C track this budget period are MDV in nature, but require additional resources to complete, hence offering under C/C Track.

Other parameters:

- Labs may select one C/C Development project per budget period, per discipline (micro, chem)
- Please note that each C/C Development project has a specific funding level (not all projects have the same funding level)
- State-proposed C/C Development projects **are not** allowed

If you are willing to participate in multiple C/C Development projects, please indicate which is your first

APPENDIX I

REQUEST FOR AUDIT REDUCTION

I. CONTACT INFORMATION

| | |
|-----------------------------|--------------------------|
| 1. Program Division Office: | 2. State Liaison Contact |
| 3. State Agency | 4. State Agency Contact |

II. CONTRACT INFORMATION

| | | | |
|--------------------------|-------------------------------------|--------------------------------------|------------------------------------|
| 1. Period of Performance | Start Date: | End Date: | |
| 2. Contract Program | <input type="checkbox"/> Human Food | <input type="checkbox"/> Animal Food | |
| 3. Audit Phase | <input type="checkbox"/> Phase I | <input type="checkbox"/> Phase II | <input type="checkbox"/> Phase III |

III. AUDIT REDUCTION

Please explain the reasons for requesting an audit reduction.

DRAFT

Please provide the number of audits planned for each type of inspection.

| HUMAN FOOD | | ANIMAL FOOD | |
|-------------------|-------|-----------------------|-------|
| Human Food GMP | _____ | PC Animal Food | _____ |
| LACF/AF | _____ | BSE | _____ |
| Seafood HACCP | _____ | Medicated Animal Food | _____ |
| Juice HACCP | _____ | | |
| Total | _____ | | |

IV. CONDITIONS OF AGREEMENT

The state and program division understand that the audit reduction is valid for the period of performance specified in this agreement.

It is the responsibility of the program division and state to report any changes to the information provided on the form. If the information provided on the form changes, the state shall notify the program division within 10 working days. The program division is responsible for reporting the changes to Office of Partnerships (OP) within 10 working days. A new Request for Audit Reduction form may be needed.

V. TO BE COMPLETED BY OFFICE OF PARTNERSHIPS

- Approved with the conditions set forth in this agreement
- Not approved for the following reasons:

DRAFT

OP Approving Official

Date

Distribution

- Director, Office of Partnerships
- Program Division Director
- Project Manager, OP
- State Liaison/District Technical Advisor
- State Agency

Appendix I
Instructions for Completing the Request for Audit Reduction

AUDIT REDUCTIONS MUST BE REQUESTED DURING THE FIRST QUARTER OF THE CONTRACT PERIOD OF PERFORMANCE OR AT THE TIME THE PROGRAM BECOMES AWARE OF THE NEED FOR A REDUCTION.

GENERAL

Use this form to obtain approval for reducing the required number of audits for the human and animal food contract inspection programs. The Program Division will complete and submit the form to the OP Audit Program Manager. If an audit reduction is needed in both feed and food, the Program Division must complete and submit separate forms for each program.

The OP Audit Program Manager will provide copies to the Program Division Director, OP Project Manager, State Liaison/District Technical Advisor, and the State Agency as notification of approval or disapproval of the request.

The request for audit reduction must be submitted and approved for each 12-month period of performance.

SPECIFIC

I. Contact Information

1. Provide the Program Division.
2. Provide the name of the Program Division person to be contacted for the information.
3. Provide the State Agency.
4. Provide the name of the State person to be contacted for the information.

II. Contract Information

1. Period of Performance (MM/DD/YYYY) - Enter the start date and end date of the contract period.
2. Select the box for the contract inspection program. When requesting a reduction in audits for the food contract program, check Human Food. When requesting a reduction in audits for the animal food contract program, check Animal Food.
3. Check the state's phase of implementation of the contract audit program.

III. Audit Reduction

1. Briefly explain the reasons for requesting an audit reduction.
2. Provide the number of audits planned for each type of inspection.

IV. Conditions of Agreement

The Program Division and state shall read and understand these conditions of agreement. It is the responsibility of the Program Division and state to report any changes to the information provided on the form. If the information provided on the form changes, the state shall notify the Program Division within 10 working days. The Program Division is responsible for reporting the changes to OP Audit Program Manager within 10 working days. A new Request for Audit Reduction Form may be needed.

V. To Be Completed By OP

This section is for OP only and should be left blank. If the audit reduction is not approved, an explanation will be provided.